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Roland Norer *Editor*

Genetic Technology and Food Safety

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Editor

Genetic Technology and Food Safety

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Introduction

The topic of Section II.D on environmental law at the occasion of the XIXth International Congress of Comparative Law in Vienna in 2014 was defined as follows: "Genetic technology and food security".

The national reporters thus had the interesting task to analyse the national legislation at the interface between genetic engineering law and food law and put it into an international or supranational context. The different regulations that thereby came to light are evidence of the various opinions and policies the societies and states have developed on this matter.

In total, 12 national reports were handed in for the section on environmental law. Geographically speaking, the subsequently presented reports in this volume may not seem representative, but they are, however, highly so from a legal point of view pertaining to possible positioning and options for action.

As a general reporter, I warmly thank the national reporters and the people who contributed to the success of this section's work. My special thanks go to Christa Preisig, MLaw, for her assistance. I would also like to thank Springer for the constructive collaboration and the publication of this volume.

I am pleased to hereby present the work of Section II.D on environmental law of the XIXth International Congress of Comparative Law 2014 with the general report and the national reports.

Lucerne, Switzerland
April, 2015

Roland Norer

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Chapter 1
Genetic Technology in the Light of Food Security and Food Safety – General Report

Roland Norer and Christa Preisig

Genetically modified organisms have been discussed controversially ever since they were subject of legislation and regulation. This reports sheds light on the question how different countries from all over the world have reacted to the emergence of the new technology of genetic engineering and how the law should respond to it. The answers to these questions of principle are highly dependent on the political and social discussions within a legal community. This is especially true for the use of GMOs in food production. What one government considers an evil to avoid is a welcome expansion of alimentary diversification to the other. Thus, there is a variety of interesting and differentiated width of legal frameworks on international, supranational (EU) and national level to be found. It is these frameworks the article will examine, primarily on the basis of the national reports that were handed in.

General Introduction

Genetically modified organisms (GMOs)[1] have been discussed controversially ever since they were subject of legislation and regulation. The emergence of a new technology usually leads to fundamental questions as to how the law should respond to

[1] A definition of GMO can be found in the Canadian Report, p. 339: "All organisms, and products thereof, produced through techniques of genetic engineering and modification including, but not restricted to recombinant DNA, cell fusion, encapsulation, macro and micro injection, gene deletion or magnification, and other techniques for altering the genetic composition of living organisms in ways, or with results, that do not occur in nature through mating or through traditional breeding techniques such as conjugation, hybridization, or transduction"; definition by the Canadian General Standards Board's Organic Agriculture Standards.

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it; the regulation of GMOs is a prime example. The answers to these questions of principle are highly dependent on the political and social discussions within a legal community which makes the matter of GMO regulation quasi to a pivotal litmus test for a state. The density of regulation, its legal instruments and the normed legal consequences that the use of GMOs entail shed light on the political processes and majority structures of a community, maybe even more so than any other legal issue.

In particular, this applies to the use of GMOs in food production. What one government considers an evil to avoid is a welcome expansion of alimentary diversification to the other. Based on this explicit or sometimes tacit key decision, there is a variety of interesting and differentiated width of legal frameworks on international, supranational (EU) and national level to be found. It is these frameworks the article will examine, primarily on the basis of the national reports that were handed in.[2] Geographically speaking, the underlying reports may not seem representative, they are, however, highly so from a legal point of view pertaining to possible positioning and options for action.

The approach for the article is as follows: In an introductory section "General introduction" the topic at hand will be developed (section "Introduction"), statistic data on the use of GMOs in food production as well as the public and governmental opinion will be laid out (section "Public opinion on GMOs"), followed by an attempt of a definition of food security and food safety (section "Position of the government on GMOs"). The second section "Legal framework" focusses on the framework set by the public international law (section "Public international law"), European law (section "EU law") and national law (section "National law"). The latter concentrates on constitutional law – if existent for the matter at hand – (section "Constitutional foundation"), statutory law (section "Statutory law"), and several principles (section "Principles"). The third section "Admission to the market" on the admission of GMO in food production elaborates on the different possibilities of restriction (section "Restriction of GMOs"), namely by prohibitions (section "Prohibitions"), general, but temporary moratoria (section "Moratoria"), safeguard clauses (section "Safeguard clauses"), subsidies (section "Subsidies for a GMO-free production") and "GMO-free zones" (section "GMO-free zones"). Further on, regulation on coexistence (section "Coexistence"), special rules on admission (section "Admission of GMOs") and threshold values (section "Threshold values") will be examined. The picture will be completed by some remarks on implementation, enforcement and the controlling regime (section "Implementation, enforcement, controlling regime"). Section "Labelling" is consecrated to legal questions concerning labelling and therefore to the assumption that the consumer must be enabled to

[2] Reporters are – in alphabetical order of the states – the following: Luc Lavrysen/Frank Maes/Piet van der Meer for Belgium; Marie-Ève Arbour for Canada; Erkki J. Hollo for Finland; Hans-Georg Dederer for Germany; Mary Dobbs for Ireland; Alberto Germanò/Eva Rook Basile for Italy; Rostam Neuwirth for Macau SAR; Claudia Colmenarez Ortiz/Sol Ortiz García for Mexico; Hans Morten Haugen for Norway; Christoph Errass for Switzerland; Anton Mingh-Zhi Gao for Taiwan; Margaret Rosso Grossman for the USA. The General Reporter thanks all the participating National Reporters for their excellent work. It is the basis for this summary which compiles the National Reports.

make a decision on his own responsibility. After setting out the labelling regime (section "Labelling regime"), special attention is given to the legislation addressing labelling fraud (section "Legislation addressing labelling fraud"). Liability is the central point of the fifth section (section "Liability"). There are various norms of administrative character (section "Administrative"), in criminal law (section "Criminal") or civil law (section "Civil") as well as product liability (section "Product liability") governing responsibility for negative consequences caused by the use of GMOs. Finally, a section "Summary" completes this report.

Introduction

"Genetic modification (also called genetic engineering) […] 'introduces one or a few well-characterized genes into a plant species and … can introduce genes from any species into a plant.'[3] Genetic engineering helps to 'speed up a naturally occurring biochemical mechanism to more quickly and precisely breed new characters into plants and animals,' albeit sometimes in ways 'unlikely to occur in nature.'"[4]

Most genetically modified crops now in production incorporate characteristics of herbicide tolerance (e.g. a plant's ability to be immune to certain herbicides) and insect resistance (e.g. a plant's ability to generate a substance to kill certain kinds of attacking vermin). Herbicide tolerance certainly prevails. What is more, research focusses on genetically modified (GM) plants with other, novel capacities such as improved conditions for cultivation (resistance to viruses and vermin, tolerance of environmental stress, e.g. drought and high salt concentrations) or changing perceptions of use ("functional food") as well as energy crops for biofuels.

"Although genetic engineering is controversial, a number of scientific reports have concluded that these varieties cause no 'adverse health or environmental effects' and that 'the processes of genetic engineering and conventional breeding are no different in terms of unintended consequences to human health and the environment.'[5] […] Indeed, three scientists whose work led to development and commercialization of genetically engineered crops received the 2013 World Food Prize, which recognizes people who improve the quality, quantity, or availability of food in the world."[6]

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[3] Report USA, p. 291, quoting Pamela Ronald, Plant Genetics, Sustainable Agriculture and Global Food Security, 188 Genetics (May 2011), pp. 11 f.

[4] Report USA, p. 291, quoting Gary Marchant et al., Impact of the Precautionary Principle on Feeding Current and Future Generations (CAST Issue Paper No. 52, June 2013), p. 11.

[5] Report USA, p. 292, quoting Pamela Ronald, p. 12. "A European organization recently indicated that 'the potential benefits of crop genetic improvement technologies are very significant,' and recommended improvements in EU policy to capture those benefits". Report USA, p. 292, quoting European Academies Science Advisory Council (EASAC), Planting the future: opportunities and challenges for using crop genetic improvement technologies for sustainable agriculture (2013), p. 2.

[6] Report USA, p. 292.

Use of GMOs in Food Production

Grossly simplified, three groups of state policies governing the use of genetically modified organisms (GMOs) in food production can be distinguished. Firstly, there are states that consider GMOs useful, sometimes they even encourage its use actively. Other states are neutral and leave GMO regulation essentially up to the market and its players. Thirdly, some countries take on a more sceptical approach that is induced by its citizens. Accordingly, they restrict or even ban the use of GMOs.

Facts and Figures

In states that find no harm in the use of GMOs, the planting and cultivation of certain seed cultures is daily routine. As the Canadian Report shows, the figures for the territory of Québec for GM soya crops are 59 % and for GM maize even 83 %.[7] The GMO-friendly USA planted 69.5 million ha of GM crops, primarily maize, soybeans and cotton, in 2012.[8] Additionally, US farmers planted GM canola, sugar beets, alfalfa, papaya and squash, making the US to the country who has approved the most GM-"events" in the world according to the US national report.[9]

In these countries, GM crops are planted chiefly for the use of food production or animal feeding stuff. This of course puts GMOs into circulation and into the food chain, if – however – indirectly through the feeding of animals. Imported GMOs are generally used to make compound feed stuffs that are fed to livestock. About 80 % of compound feed stuffs contain GMOs.[10]

However, even if states are not opposed to the use of GMOs in food production, this does not automatically mean that GM crops are widely in use. Ireland illustrates this quite clearly[11]: Even though the Irish legislator has a positive approach concerning GMOs, very few field trials have been carried out and cultivation of GM crops has not occurred (despite general EU authorisation for a number of crops over the years). Currently there is no GM cultivation within Ireland. There have in fact been several authorisations of field trials providing for deliberate release of GMOs into the environment, but they have not been conducted. Furthermore, GM animals are not authorised in the EU or Ireland. As to GM feed, approximately 2.3 tonnes of the raw materials used in compound feed in Ireland were from GM crops authorised in

[7] Report Canada, p. 339.

[8] See Report USA, p. 293, with further references. According to the report, "[i]n 2012, GM varieties made up 88 % of all corn, 93 % of soy and 94 % of upland cotton".

[9] Report USA, p. 293, stating that GM-events are approved for release into the environment, cultivation, food and feed.

[10] Report Belgium, p. 128.

[11] Report Ireland, p. 177.

the EU and more than 90 % of protein feed for livestock contained EU authorised GM varieties in 2010.

In contrast to the Irish approach, in Germany, the use of GMOs is virtually confined to so-called "contained use", which means that GMOs are used in laboratories, growth-rooms, glasshouses, animal units or industrial plants only. Throughout Germany, there exist several thousand contained use facilities. Data is provided by the German States (the "Länder")[12] concerning the contained use of GMOs.[13] In Bavaria for instance, there exist currently 796 contained use facilities, of which 551 can be attached to public operators (e.g., universities) and 236 to private operators (e.g., Max-Planck-Institutes, major research institutions, firms).[14] In 2013, no GM plants were released into the environment, neither for research nor for commercial (e.g. agricultural) purposes.[15] In fact, since 2007, a sharp decline in the numbers of field trials with GM plants can be noted.[16] On the other hand however, cultivation of Bt corn (MON810) increased slowly but steadily for 4 years between 2005 (342 ha) and 2008 (3173 ha).[17] This development was stopped abruptly in 2009 due to a safeguard measure adopted by the Federal Office of Consumer Protection and Food Safety.[18]

Even more restrictive are countries with a strongly critical approach concerning GMOs, e.g. Switzerland.[19] In Switzerland there have only been very few experimental field releases of GMO and only a handful of GM products have been approved.[20] Up to **now**, only four food products have been admitted (three varieties of maize and one of soya).[21] What is more, there are no approved GMOs in agriculture at the moment. The last application that has been discussed was in relation to Monsanto's oil canola line GT73. It was not admitted by the Ministry of Environment (decided in December 2012) even though GT73 is allowed in the EU.

Somewhat in between those policies are the approaches of states such as Macau SAR that do not have any specific regulation on GMOs. This might be due to respective geographic and historical factors.[22]

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[12] See http://www.lag-gentechnik.de/index.html

[13] Report Germany, p. 75.

[14] http://www.stmug.bayern.de/umwelt/gentechnik/bayern/anlagen.htm

[15] Report Germany, p. 76.

[16] http://www.transgen.de/anbau/deutschland/1714.doku.html

[17] http://www.bvl.bund.de/DE/06_Gentechnik/01_Aufgaben/02_ZustaendigkeitenEinzelneBereiche/04_Standortregister/Auswertung_Stareg/gentechnik_standortregister_HG_Auswertung_Stareg_node.html

[18] Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL.

[19] Report Switzerland, pp. 260 ff.

[20] Cf. http://www.bafu.admin.ch/biotechnologie/01760/08936/index.html?lang=de

[21] Cf. http://www.bag.admin.ch/themen/lebensmittel/04858/04863/04883/index.html?lang=de

[22] Cf. Macau SAR, where due to the size of the territory and its economic structure there is hardly any agriculture nor much food production. This means that there are no or only few facts and figures available on the use of GMOs. So the local concerns in Macau are usually about food quality und food safety in general and less about the specific role of GMOs applied to food processing; Report Macau SAR, pp. 424 ff.

All in all, GM crops "are 'the fastest adopted crop technology in the history of modern agriculture.'"[23] "Since 1996, international production increased" significantly from 1.7 million ha to 170 million ha in 2012, when the global value of GM seed was estimated at roughly USD 15 million.[24] Leading countries were the USA, Brazil, Argentina, Canada and India. For comparison, Spain as a Member State of the European Union produced 116,000 ha of GM corn. In 2012, the gradual change to developing countries could be noted: farmers in 20 emerging nations "grew the majority (52 %) of GM crops. In China, 7.2 million farmers produced Bt cotton ([an equivalent] to 4 million ha); 93 % of cotton in India (10.8 million ha) was Bt. Four African countries grew GM crops in 2012: South Africa (2.9 million ha), Sudan, Burkina Faso and Egypt. Five conducted field trials, but [overall] GM cultivation remains limited" on the African continent.[25]

In 2011, a total of 160 Mio ha of the worldwide agricultural area was cultivated with GM crops whereof 95 % of the produced GMO was harvested in only six states (USA, Brazil, Argentina, India, Canada and China). Soya is by far the most important crop plant (around 75 million ha), followed by maize (51 million ha), cotton (24.7 million ha) and canola (8.2 million ha). Up to 75 % of the worldwide soya production is genetically modified by now. Europe however has a comparatively low share (below 0.1 %) of areas cultivated by GM crops, it only accounted to 0.115 million ha in 2011 and has been stagnating ever since.[26]

In countries that do not or only on a very small scale cultivate GM crops, the issue is mainly relevant for exports or in science. Taiwan for example imports 2.5 million tonnes of soybeans and 4.8 million tonnes of corn each year. An estimated 93 %, respectively 40 % of these imports are genetically modified.[27] Taiwan has a domestic GMO research industry including among others aquaculture crops or livestock, but only soya and corn have been approved as admissible food by the Taiwan Food and Drug Administration. Consequently, other GM crops and livestock remain at the pre-market stage of research and development.

It can be assumed that the differences between states and regions are significant. The disputes among the EU Member States and their respective margins of appreciation impedes consensus and does not allow to establish homogenous, agreed upon legal and factual grounds. This is due to the fact that up to now, each Member State could de facto and de jure position itself according to its own appreciation. This explains why there is currently no cultivation of GMOs for example in Belgium,[28] mainly because there are no GM crops approved for cultivation that are

[23] Report USA, p. 292, quoting Gurdev S. Khush, Genetically modified crops: the fastest adopted crop technology in the history of modern agriculture, Ag. & Food Security 1, (2012), passim.

[24] Report USA.

[25] The numbers and figures in this paragraph are all taken from the Report USA, pp. 292 f.

[26] Daniela Nowotny, Gentechnikrecht, in: Roland Norer (ed.), Handbuch des Agrarrechts, 2nd edition (2012), p. 392 with further references. A list of GMOs authorised for GM food and feed products in the EU is available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

[27] Report Taiwan, p. 387.

[28] Report Belgium, pp. 128 f.

relevant for Belgian agriculture, whereas in Germany,[29] GMOs are handled less restrictively.

Public Opinion on GMOs

Not only do state policies concerning GMOs differ, public opinion on genetic engineering is similarly heterogeneous, even more so since it often is a controversial question. Thus, the public debate may influence a state's approach for the regulation of the technology. Public opinion on the use of GMOs for food production is polled on a regular basis. The data suggests that the topic evokes divergent reactions that differ from state to state. Especially consumer organisations[30] and professional agricultural organisations[31] in some states, especially within the EU, but also in developing countries view genetic engineering very critically.

Eurobarometer surveys on bioengineering spell out the concerns European citizens have concerning GMOs in general and GM food in particular. There are a few noteworthy discrepancies between the EU average on the one hand and the single Member States on the other, as the hereinafter examined example of Germany shows.

According to a Eurobarometer survey held in 2010,[32] in the EU27, an average of 54 % think that GM food is neither good for them nor their families, in Germany it is 69 % of the respondents. Only 43 % of the EU27 average agree (compared to 37 % who disagree) that GM food helps people in developing countries (Germany: 41 % who agree, 46 % who disagree). 58 % of respondents in the EU27 average think that GM food is not safe for future generations (Germany 72 %). Almost in line with the EU27 average of 70 %, 69 % of respondents in Germany agree that GM food is fundamentally unnatural. Only 22 % of the respondents in the EU27 average (Germany: 17 %) agree and 59 % disagree (Germany 74 %) that GM food is safe for one's health. In fact, 66 % of respondents in the EU27 average (Germany 71 %) are worried about GMOs in foods and beverages.[33] Accordingly, 23 % of the respondents in the EU27 average (in Germany only 20 %) believe that the development of GM food should be encouraged whereas 61 % (Germany 72 %) think it should not.

As the survey shows, public awareness of GM food is exceptionally high in some EU-Member States like Germany. However, the German public appears to be confident about being able to assess the advantages and disadvantages of GM food. It can still be noted that the German public tends to be much more critical about GM food

[29] Report Germany, pp. 75 ff.

[30] http://www.beuc.org/Content/Default.asp

[31] http://www.copa-cogeca.be

[32] European Commission (ed.), Eurobarometer 73.1: Biotechnology (2010) (Special Eurobarometer 341).

[33] European Commission (ed.), Eurobarometer 73.5: Risiken im Lebensmittelbereich (2010), p. 2.

than the EU average.[34] All in all, the Eurobarometer survey "reveals an overall suspicion of GM foods amongst the European public".[35]

Public opinion can also differ within a state itself as the example of Belgium illustrates. The opinion on the use of GMOs in food production is in general not negative, whereas it is seen slightly less positive in the Walloon Region than in the Flemish Region; but according to a survey, overall, a rather positive attitude towards the use of certain GMOs in food production can be observed. There is, however, also a strong minority opinion against GMOs.[36] The situation in Canada is comparable, which means that different attitudes can be observed in some provinces whereby environment protection is predominant (e.g. Québec or British-Columbia).[37]

In Taiwan numerous studies on public perceptions of GM products and respective research and development practices have been conducted.[38] In 2000, the Department of Health (DOH) published a study that examined public perceptions of GM food and its safety.[39] The results showed that 68.1 % of respondents had heard of GMO. However, more than half did not have any clear or deeper knowledge on bioengineering. 61.6 % of the respondents expressed concern about the safety of GM food. Some 66.9 % were worried about the potentially negative effects on human health that could result from the consumption of GM crops.

Besides these essentially geographically, culturally and sociologically induced differences, differentiating surveys show significant variations in public opinion on different products and application of biotechnology. Thus, most surveys indicate that the acceptance for the use of bioengineering is far higher for medical applications than for agricultural or alimentary purposes. Within the latter areas though, public opinion also differs depending on the nature of the crop and the context of its use.

Irrespective of these differentiations, European States seem more opposed to bioengineering than countries on any other continent. In Switzerland for example,

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[34] Accordingly, an opinion poll illustrates that 82 % of the respondents in Germany consider the label "ohne Gentechnik" ("without genetic engineering") a good choice, which means that the majority of the German public is highly interested in consumer information on whether products are free of GMOs or not; available at http://www.gentechnikfreie-regionen.de/hintergruende/studien/umfragen.html. Report Germany, p. 78.

[35] Eurobarometer 73.1, p. 18 (n. 32).

[36] Report Belgium, p. 129.

[37] Report Canada, p. 340. The Canadian Government made a public consultation in 2012–2013 in order to evaluate the prospect of importing "low level presence" of GM foods on a new level. The consultation aimed at gathering the outlooks of all Canadian citizens, both public and stakeholders, on this controversial subject. The survey made clear that there is a wide array of opinions expressed by different stakeholders, each representing a variety of interests which make the task of reaching a compromise difficult, Report Canada, pp. 339 f.

[38] Report Taiwan, pp. 388 f.

[39] The Department of Health (衛生署) (2000), The Study on Public Perception on Biotechnology and GMO Food (民眾對生物科技及基因改造食品的認知及態度), available at http://food.doh.gov.tw/gmo/gallup.htm

according to the latest survey dating from 2013 conducted by the Federal Technical Institute of Zurich, GM food ranks third on the list of concerns of the Swiss population.[40] In addition, a highly controversial public debate between supporters and opponents has broken out at the occasion of the Gene Protection Initiative. Even the Swiss Federal Administration itself could not find a homogenous position.[41] That bioengineered food faces so much refusal cannot be pinned down to one single reason. It is expressed with a wide range of protest campaigns, manifested as public protests or even vandalism of GM crops in the UK, France or Switzerland.[42]

As opposed to the situation in the EU, consumers in the United States seem less concerned with the issue of GMOs. "American consumers often display a 'dismal level of basic knowledge' about food and agriculture, and they know even less about the prevalence of GM foods in American supermarkets or about the effects of GM ingredients in food. […] Indeed, although many consumers generally accept GM food and others have little knowledge about these foods, an increasing segment of the population is demanding that GM foods be labeled."[43] In 2012, "a representative survey of US consumers indicated that almost half approved the use of biotechnology", especially if it helped to grow more crops and thus contributed to food security.[44] Acceptance of GM products is higher if they offer health benefits, taste better or lead to a reduction of pesticide use.[45]

From the farmers' point of view, "the high percentage of American farmers who cultivate GM corn, soy and cotton – [around 90 %] – indicates that these crops have achieved acceptance. Farm income benefits of major GM crops (corn, soy, cotton and canola) include cheaper and easier weed control, lower production costs, less damage from pests and sometimes higher yields".[46] "Despite the benefits of GM technology, acceptance is not uniform. Concern about the possibility of 'contamination' of organic, identity-preserved or traditional crops with GM material raises issues of coexistence. That is, producers want to choose the type of crop they cultivate, without fear that pollen drift or admixture of GM and other seeds will affect the purity and marketability of their crop."[47]

Overall, the national reports show that there is widespread concern about GMO research and development as well as GM food. The research also suggests that there are divergent views on GMO food and products as well as between states and

[40] Cf. http://www.srf.ch/news/schweiz/wovor-haben-sie-angst

[41] Report Switzerland, p. 263.

[42] Michael Cardwell, Public Participation in the Regulation of Genetically Modified Organisms: A Matter of Substance or Form?, 12 Envtl L. Rev. (2010), p. 25.

[43] Report USA, p. 296.

[44] Report USA, p. 295, citing Alan McHughen, Public Perceptions of Biotechnology, 2 Biotechnology J. (2007), pp. 1105 f.

[45] Report USA, p. 296.

[46] Report USA, p. 293.

[47] Report USA, p. 294, citing Margaret Rosso Grossman, The Coexistence of GM and Other Crops in the European Union, 16 Kan. J.L. & Pub. Pol'y (2007), p. 324.

regions. In any case, it is not too far-fetched to conclude that the higher the level of knowledge of farmers but also consumers is, the higher is the tendency that public opinion is more critical.

Position of the Government on GMOs

The public opinion is not the only aspect that differs considerably among the states examined, the governments in these countries do not have homogenous positions either.

An actively positive position for example can be noted in the Canadian executive. Along with the United States and Argentina, Canada has taken the lead in the production and commercialization of GMOs.[48] As a major exporter, it has opposed the EU upon WTO scene, advocating for the removal of obstacles to trade linked with the risk/benefice ratio that is carried on by national and supranational regulators. Surveys, WTO litigation and the absence of labelling (e.g. following the example of the EU) indeed suggest that the bioengineering industry enjoys a massive support from the government and, overall, the population.

"The US government recognized the potential of crop biotechnology in its early regulatory documents […] and has consistently supported biotechnology".[49] "The US recently emphasized the role of biotechnology in global food security by supporting the Joint Statement on Innovative Agricultural Production Technologies, particularly Plant Biotechnologies."[50] According to this statement, the focus lies on "transparent science-based regulations, consistent with principles and guidelines of the Codex Alimentarius Commission, synchronization of authorizations for new products, continued research, and other cooperation."[51]

Other governments have a positive approach as well, yet they seem to act more gingerly. So generally the Irish governments have taken a "positive but precautionary approach" to the use of GMOs.[52] In any case, the positions and strategies depend strongly on the respective political constellation. A recent government stated in 2009 that it would aim for a GM-free Ireland, but this was under a different coalition that involved the Green Party. Following the departure of the Green Party from the coalition, the government re-evaluated its position in relation to GMOs so that it is currently more positive and essentially supports the position at the EU level, facilitating authorisations of GM food, feed and crops provided they follow risk assess-

[48] Report Canada, p. 339.

[49] Report USA, p. 297.

[50] Report USA, p. 297, citing a link from http://www.fas.usda.gov/itp/biotech/biotech_trade.asp. Other supporting governments are Australia, Brazil, Canada, Argentina and Paraguay according to the Report USA.

[51] Report USA, p. 297, quoting Codex Alimentarius, Foods derived from modern biotechnology, 2nd ed. (2009) (collecting principles and guidelines), ftp://ftp.fao.org/docrep/fao/011/a1554e/a1554e00.pdf

[52] Report Ireland, p. 177.

ments in accordance with the precautionary principle. According to its previous position, Ireland would have abstained. Yet when the EU considered its proposal to allow for Member States to opt out from cultivation,[53] although Ireland did raise concerns, these related to technical aspects and not the overall aim of the proposal. Indeed Ireland was part of the group of Member States who requested that such an approach be considered.

The opposite opinion is held in Austria. In accordance with the great scepticism of the people, the Austrian federal government has taken on an actively negative position towards GMOs. It pursues a policy of actively opposing to GMOs and does so by any legal means which include moratoria, bans in some of the federal states (safeguard clauses), regulation on bans, specific bioengineering legislation guided by the precautionary principle and even appeals with the Court of Justice of the European Union.[54]

Then again, some governments hold opinions differing from the public perception of GMOs. The German Report hints to the fact that the federal government takes a remarkably more differentiated view on GM food and their risks and benefits than the German public with regard to the impact of agricultural biotechnology on secure world-wide food supply. On the other hand, perhaps due to the German public's strong suspicions of GM food, the government seems to be quite careful in avoiding a clear cut position pro or contra GM food as far as it concerns global food security.[55] Thus, the Federal Government refers to scientific studies according to which GM plants can contribute to global food security but acknowledges at the same time that there are other studies which suggest that this question depends on the local context within which GM plants are used.[56] This illustrates once more that the position is subjected to the number of representatives in favour of GMOs.[57] Currently, the German government is once again more cautious towards agricultural genetic engineering in general and GM food in particular. Although biotechnology is identified as a leading market, the governing parties accept the population's reservations towards "Grüne Gentechnik" (green genetic engineering).[58] Furthermore, some Länder governments may be significantly more critical than the government on the federal level.

The different regions in Belgium do not have a uniform approach to the use of GMOs in agriculture either.[59] The Walloon and Brussels-Capital Region have implemented coexistence regulations that are meant to discourage the cultivation of GM crops. The Flemish region, however, follows a different path. The Flemish govern-

[53] See section "Opt-out" below.

[54] See overview in Daniela Nowotny, pp. 393 f. (n. 26).

[55] Cf. in detail Report Germany, pp. 78 ff.

[56] BT-Drs. 17/8819 of March 1, 2012, p. 4.

[57] On the basis of the different coalition agreements of the German federal government since 1998, cf. Report Germany, p. 79.

[58] Deutschlands Zukunft gestalten. Koalitionsvertrag zwischen CDU, CSU und SPD, 18. Legislaturperiode (2013), pp. 19 and 123 ff.

[59] Report Belgium, pp. 128 f.

ment does not stimulate the use of GM crops, but is of the opinion that GM crops that are proven to be safe and have a market authorisation should be available for farmers, i.e. to allow them freedom of choice. The coexistence legislation in Flanders neither encourages nor discourages the use of GM crops, and thus also enables freedom of choice.

Finally, the issue of GMOs is also addressed with a pragmatic, rather matter-of-fact approach. The Taiwan government thus recognises the potential risks of GMO foods or products and has therefore adopted a moderate approach in adopting a regulatory framework for GMO research and development, GM food and production. Accordingly, both appropriate incentives and regulations have been provided, rather than merely restrictive or punitive provisions.[60] It seems that the Taiwanese government unites public opinion as well as contemporary scientific findings in its regulation of bioengineering and has therefore adapted a balanced if not to say neutral position.

The outlined examples outline the argumentative scenery in which governments find themselves when it comes to adopting a strategy for the use of GMOs. In order to form their positions on GMOs, governments face the challenge to assess the use and risks of the technology. By doing so, they rely on scientific findings while having to bear public opinion in mind. Research suggests that genetic technology may contribute to food security and should therefore be fostered in order to reduce hunger. Nevertheless, worries are expressed when it comes to the safety of GM food. Both notions are crucial for the topic of genetic engineering in context with food. The following chapter will therefore have a closer look at their normative implications and the consequences for governments and legislations.

Food Security and Food Safety

Both notions have increasingly been part of (nutrition) policy and legal discourse during the last few years. The not uncommon involuntary amalgamation or confusion justifies a short clarification of the terminology for the purposes of this article.

"**Food security**"[61] is commonly used to refer to the availability of food including the securing of one's access to food. It is often monopolised by the human rights discourse. Thus, food security is generally understood as to refer to the Right to

[60] Report Taiwan, p. 389.

[61] German: „Ernährungssicherheit"; French: „sécurité alimentaire". The notion must be distinguished from the term „food sovereignity" (German: „Ernährungssouveränität"; French: "souveraineté alimentaire") that is currently being discussed intensively as political concept. See Roland Norer, Ernährungssouveränität – vom politischen Modewort zum Rechtsbegriff?, BlAR (2011), pp. 13 ff.; see also Christian Häberli, Rechtliche Grundlagen für die Ernährungssicherheit in der Schweiz, BlAR (2013), pp. 181 ff.

food[62] or, inversely, the Right to be free from hunger.[63] This right is enshrined in Art. 25(1) of the Universal Declaration of Human Rights (UDHR)[64] and the legally binding International Covenant on Economic, Social and Cultural Rights (ICESCR, UN Pact I).[65]

In 1996, 180 nations gathered at the Food and Agriculture Organisation of the United Nations headquarter (FAO) to eradicate hunger by reducing the number of undernourished people by half by 2015. The conclusions of this meeting are summarized in two documents, the Rome Declaration on World Food Security and the World Food Summit Plan of Action.[66] Prior to the 1996 meeting, the definition of food security had never been the object of serious reflection. According to the Committee on World Food Security (CFS), an intergovernmental forum within the UN system,[67] food security exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life.

According to the FAO,[68] the four key aspects, which need to be met cumulatively, are:

- Physical availability of food: Food availability addresses the "supply side" of food security and is determined by the level of food production, stock levels and net trade.
- Economic and physical access to food: An adequate supply of food at the national or international level does not in itself guarantee household level food security. Concerns about insufficient food access have resulted in a greater policy focus on incomes, expenditure, markets and prices in achieving food security objectives.
- Food utilisation: Utilisation is commonly understood as the way the body makes the most of various nutrients in the food. Sufficient energy and nutrient intake by individuals is the result of good care and feeding practices, food preparation, diversity of the diet and intra-household distribution of food. Combined with

[62] Cf. Report USA, p. 307, quoting UN Special Rapporteur on the Right to Food Olivier de Schutter: "The right to food is a human right recognized under international law which protects the right of all human beings to feed themselves in dignity, either by producing their food or by purchasing it." Elements of this right include availability of food, accessibility (both economic and physical), and adequacy (to satisfy dietary needs). Article available at http://www.srfood.org/en/right-to-food. Quote taken from the Report USA.

[63] See Report Macau SAR, p. 426.

[64] Art. 25(1) of the Universal Declaration of Human Rights, GA Res. 217(III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948).

[65] Art. 11(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR), adopted on December 16, 1966, 993 UNTS 3 (1966).

[66] See Food and Agriculture Organisation of the United Nations, Rome Declaration on World Food Security and World Food Summit Plan of Action (1998) [http://www.fao.org/docrep/003/w3613e/w3613e00.HTM].

[67] See Art. III(9) FAO Constitution; http://www.fao.org/cfs/en/

[68] FAO, An Introduction to the Basic Concepts of Food Security (2008): http://www.fao.org/docrep/013/al936e/al936e00.pdf

good biological utilisation of food consumed, this determines the nutritional status of individuals.
- Stability of the other three dimensions over time: Even if a person's food intake is adequate today, the individual is still considered to be food insecure if the access to food on a periodic basis is inadequate, thus risking a deterioration of the nutritional status. Adverse weather conditions, political instability or economic factors (unemployment, rising food prices) may have an impact on a person's food security status.

"In 2006, the US Department of Agriculture (USDA) adopted new terms to describe 'ranges of severity of food insecurity' in the United States. High food security means no reported problems with food access. Marginal food security involves one or two indications of anxiety about food sufficiency, but without changed diet or food consumption. Low food security is indicated by reduced 'quality, variety or desirability of diet,' but with little or no indication of reduced consumption. Very low food security is characterized by 'multiple indications of disrupted eating patterns and reduced food intake.'"[69] Food insecurity is closely related to food prices. According to this classification, the US, Norway and France are the most food secure countries in the world.[70] Furthermore, the American Report stresses the narrow and important linkage between food aid on the one hand and food waste and loss on the other.

"**Food safety**"[71] – in contrast to food security – relates to human health, i.e. whether food is safe for consumption by humans or whether it might threaten human health.[72] In contrast to food security this term deals with all aspects of handling of food to prevent food borne illness, i.e. to provide safe food.[73]

If compared, the two notions at hand can be summed up as follows: Food security can be defined as being primarily concerned with the "adequate supply and sufficient availability of food", i.e. quantitative aspects of food supply. By contrast, food safety can be understood as being predominantly concerned with the requirement that the food supplied does not harm those who consume it, i.e. qualitative aspects of food supply.[74]

The Report of Macau SAR made a relevant point in remarking that the two concepts are not only different but also closely related. This, in particular, when one

[69] Report USA quoting ERS, USDA, Definitions of Food Security; http://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/definitions-of-food-security.aspx-assistance/food-security-in-the-us/definitions-of-food-security.aspx. See Report USA, p. 299.

[70] Report USA, p. 300, citing Economist Intelligence Unit, Global food security index 2013 (2013), p. 6.

[71] German: „Nahrungsmittelsicherheit"; French: „sécurité sanitaire des aliments".

[72] Report Germany, pp. 80 f.

[73] It has been defined as follows: "Food safety is generally recognized as the biological, chemical or physical status of a food that will permit its consumption without incurring excessive risk of injury, morbidity or mortality." Christine Boisrobert et al. (eds.), Ensuring Global Food Safety: Exploring Global Harmonization (2010).

[74] See Report Macau SAR, p. 426.

approaches the issue from the perspective of sustainable development and the principle of inter-generational equity.[75] These issues have been recognized in the human rights discourse by combining quantitative and qualitative considerations related to food security by the development from a "right to food" to a "right to adequate food".[76] This right was defined by the UN Committee on Economic, Social, and Cultural Rights (CESCR) as follows: "The availability of food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances, and acceptable within a given culture; The accessibility of such food in ways that are sustainable and that do not interfere with the enjoyment of other human rights."[77]

In the same context, the UN Economic and Social Council formulated General Comment No. 12 on the Right to Adequate Food in 1999, which imposes obligations upon states that are reflected in the FAO Voluntary Guidelines on the Right to Food dating from 2004. Obligations include negative ones (not to arbitrarily deprive people of their right to food) and positive ones (to facilitate and promote access and utilisation), which together will promote food security nationally and internationally.[78]

In view of the advent of the invention and application of new technologies in the production of food, such as those to be found in GM food, nanofoods or functional foods, these obligations constitute an important development for the concern of food security. It is in the light of these novel foods that the contacts between the two concepts culminate since these novel products are often invoked as a means to secure the food supply for a steadily growing world population on the one hand while at the same time they are also considered to possibly bear unintended long-term consequences or various risks for food safety. Therefore food safety and food security are closely **intertwined concepts**. It only makes sense to address concerns about food safety if food supply is secured in the first place as it may become necessary that in the attempt to secure the food supply, one may be forced to compromise on food safety, i.e. the quality of the food supplied. Therefore food safety is seen as an essential and integral component of food security.

Along with these international implications and definitions, **national legislators** sometimes include one or both of the two terms in their national law. The Canadian government for example endorsed the definition of the Committee on World Food Security as part of their international commitment.[79] Another example is Macau

[75] See Report Macau SAR, pp. 426 f.

[76] See e.g. Stefania Negri, Food Safety and Global Health: An International Law Perspective, 3 Global Health Governance 1 (2009); George Kent, Freedom from Want: The Human Right to Adequate Food (2005); Kerstin Mechlem, Food Security and the Right to Food in the Discourse of the United Nations, (2004) 10 European Law Journal 631; Jean Ziegler/Christophe Golay/Claire Mahon/Sally-Anne Way, The Fight for the Right to Food: Lessons Learned (2011).

[77] Committee on Economic, Social and Cultural Rights, General Comment No. 12, E/C.12/1999/5 (May 12, 1999), para. 8.

[78] Report Ireland, p. 175.

[79] Geneviève Parent, Droit économique et sécurité alimentaire: un couple mal assorti?, (2012) 4 Rev. int. de droit écon., p. 15 (at p. 16). According to Parent, this definition is sufficiently broad to

SAR,[80] where the legislator puts it like this: "This law regulates the supervision and administration, the preventive measures, the control and treatment of the risks and the mechanisms for the handling of incidents in the field of food safety, in order to guarantee the health and safety of the lives of people."[81]

Where there is no legal definition of food security or food safety, as for example in Belgium, Ireland or Mexico, the terms and the concept that lies beneath have often found their ways into official documents such as White Books or special programs.[82]

The functional attribution of the terms in national hierarchies of norms illustrates – exemplarily described on the basis of German law that, incidentally, does not define the terms – that the notion of food security recurs to the constitutional level. It is mentioned only occasionally, e.g., in the Basic Law (Grundgesetz – GG),[83] i.e. in the Federal Constitution,[84] and in the Bavarian Constitution (Bayerische Verfassung – BV).[85,86] The case is different with food safety which has found its way into German and other national laws, mostly in the form of national legislation on foodstuffs.[87] In Norway there is no recognition of the right to food in the national Constitution, but a proposal for including economic, social and cultural rights in the Norwegian Constitution does recommend that food is specified as one of the elements for an adequate standard of living.[88]

Insofar, both terms have its justification **in context with the topic of GMOs** that this article attempts to elucidate. On the one hand, there is a connection in the developmental and nutrition policy context where the use of GMOs for food production can – by means of an increased area of cultivation and more crops – lead to a better

address problems that are specific to economically developed countries, such as obesity, and, for our purpose, GM product's consumption.

[80] See Report Macau SAR, p. 428.

[81] Art. 1 Macau Food Safety Law (MFSL) [食品安全法(第5/2013 號法律) or Lei de segurança alimentar (Law No. 5/2013)], Official Bulletin No. 17/2013, Series I (April 22, 2013), pp. 259–69.

[82] See the White Book about Agriculture of Flanders, Report Belgium, p. 129; The White Paper on Irish Aid in 2006, Report Ireland, p. 175; Strategic Project for Food Security (SPFS) [Proyecto Estratégico para la Seguridad Alimentaria (PESA)] in connection with the Food and Agriculture Organisation's (FAO) Special Program for Food Security, Report Mexico, p. 364.

[83] Grundgesetz für die Bundesrepublik Deutschland (BGBl. 1949 p. 1).

[84] See Art. 74(1)(17) GG which confers concurrent legislative powers upon the Federation in the area of "ensuring the adequacy of food supply", Report Germany, p. 81.

[85] Verfassung des Freistaates Bayern (GVBl. 1946 p. 333), Report Germany, p. 81.

[86] See Art. 83(1) BV which provides that food security facilities are within the realm of municipal self-government, Report Germany, p. 81.

[87] See for instance in Germany Sec. 1(1)(1) Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch LFGB, BGBl. 2013 I p. 1426 („German Food, Consumer Good and Feed Act"). In Taiwan the Act Governing Food Sanitation, amended June 19, 2013, contains numerous – sometimes explicit – references to food safety. As to the relation between the terms food sanitation and food safety, see Report Taiwan, pp. 390 ff. In Canada food safety is well alive in federal and provincial legislation, case-law and scholarship, Report Canada, p. 341.

[88] Report Norway, p. 251.

and more secure food supply, especially in emerging and developing countries. Industrialised countries on the other hand focus on the aspect of food safety, thus concerns about GM food possibly presenting a threat for health prevail. The national reports that were handed in have emphasised either food safety or food security, which is why the article will address both aspects when lining out the legal framework as well as the specific norms regulating admission, labelling and liability in context of GMOs.

Legal Framework

Public International Law

According to Art. 11(1) International Covenant on Economic, Social and Cultural Rights (**ICESCR**; UN Pact I)[89] the States Parties recognize the right of everyone to an adequate standard of living for himself and his family, including adequate food, clothing and housing and to the continuous improvement of living conditions. According to the above-mentioned General Comment No. 12 of the Committee on Economic, Social and Cultural Rights (CESCR), "the core content of the right to adequate food implies: The availability of food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances, and acceptable within a given culture".[90] The States Parties to the present Covenant, recognising the fundamental right of everyone to be free from hunger,[91] shall take individually and through international co-operation, the measures which are needed inter alia to improve methods of production, conservation and distribution of food. Art. 11 of UN Pact I requires governmental measures but does not grant citizens any justiciable right to food.[92] Art. 12(1) ICESCR and Art. 24(1)(1) Convention on the Rights of the Child (**CRC**)[93] which enshrine the right "to the enjoyment of the highest attainable standard of physical and mental health" are closely related to food security as well.[94] Art. 24(2)(c) CRC is even more explicit obliging States to "take appropriate measures … to combat … malnutrition … through the provision

[89] N. 64.

[90] N. 77.

[91] Cf. Christine Breining-Kaufmann, Hunger als Rechtsproblem – völkerrechtliche Aspekte eines Rechtes auf Nahrung (1991), relating to Art. 11 UNO Pact I, pp. 59 ff. See also Marco Borghi/Letizia Postiglione Blommestein (eds.), For an effective Right to adequate food (2002); Marco Borghi/Letizia Postiglione Blommestein (eds.), The right to adequate food and access to justice (2006); Christophe Golay/Melik Özden, Le droit à l'alimentation (2006).

[92] Report Switzerland, p. 266.

[93] Convention on the Rights of the Child, adopted by the General Assembly of the United Nations on November 20, 1989, 1577 UNTS 3 (1989).

[94] Cf. General Comment No. 14 (2000) of the CESCR (n. 77).

of adequate nutritious foods". Thus, concrete requirements for the handling of GMOs can be derived neither from Art. 11 and 12 ICESCR nor from Art. 24 CRC.

The **International Treaty on Plant Genetic Resources for Food and Agriculture**[95] has a similar aim as Art. 11(2) ICESCR as such does not provide requirements for handling GMOs either. However, it provides evidence that it may be an advantage to cultivate conventional organisms alongside GMOs. According to Art. 6 of the treaty, plant genetic resources for food and agriculture are the essential raw materials for adapting to unpredictable environmental changes and future human needs. Therefore, the parties shall develop and maintain appropriate policy and legal measures that promote the sustainable use of plant genetic resources for food and agriculture. These include the conservation of intra- and inter-specific variations and the expanded use of local and locally adapted crops, varieties and underutilised species. The aim is to obtain a wide range of plant genetic resources to protect food security.[96]

Another point of reference is to be found in the **FAO's Constitution**, according to which Member States of the Food and Agriculture Organisation (FAO)[97] are expected to take "separate or collective action" for the purpose of "ensuring humanity's freedom from hunger".[98]

In addition, national food law is influenced by the **Codex Alimentarius Commission**, which provides a global structure formation for international administrative law. The Codex Alimentarius Commission, established by FAO and WHO in 1963, develops harmonised international food standards, guidelines and codes of practice to protect the health of the consumers and to ensure fair practices in the food trade.[99] The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organisations.[100] The standards adopted by the Codex Alimentarius Commission are non-binding recommendations (soft law). They may become national law by incorporation or reference.[101] In the Member States through Art. 3 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement),[102] the

[95] International treaty on plant genetic resources for food and agriculture, FAO, available at ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf

[96] See Christoph Errass, Elemente zum Verständnis von Art. 7 GTG. Auslegung des schweizerischen Rechts einschliesslich gewisser völkerrechtlicher Bestimmungen, in: Rainer J. Schweizer/Christoph Errass/Stefan Kohler, Koexistenz der Produktion mit und ohne gentechnisch veränderte Organismen in der Landwirtschaft (2012), pp. 188 f.

[97] Constitution of the Food and Agriculture Organization of the United Nations.

[98] Preamble of the FAO Constitution.

[99] http://www.codexalimentarius.org/codex-home/en/

[100] Cf. comprehensively Tilman Makatsch, Gesundheitsschutz im Recht der Welthandelsorganisation (WTO). Die WTO und das SPS-Übereinkommen im Lichte von Wissenschaftlichkeit, Verrechtlichung und Harmonierung (2004), pp. 204 ff.

[101] Report Switzerland, p. 267, with further references.

[102] Appendix 1A.4 of the Agreement establishing the World Trade Organization.

standards of the Codex Alimentarius Commission have now gained increased validity.[103]

The objective of the **Cartagena Protocol on Biosafety (Cart. Prot.)**[104] to the Convention on Biological Diversity (CBD) is to ensure an adequate level of protection with regard to the transfer, handling and use of especially GMOs.[105] The focus is on the cross-border movement of GMOs. The protocol thus mainly aims at regulating – chiefly on a procedural level – the transboundary movement of GMOs in order to preserve the environment (Advance Informed Agreement Procedure AIA; Art. 7 ff. Cart. Prot.).[106] The protocol therefore focusses on the introduction of GMOs into the environment. GM food and feed as well as food and feed derived from GMOs are subject to the special procedure and the risk assessment set out by Art. 11 Cart. Prot. According to Art. 11(4) Cart. Prot., a party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of the Protocol. The rules applicable in case of damage caused by the transboundary movement of GMOs are laid down in the NKP.[107]

The agreement establishing the **World Trade Organisation** has significant impact on food law, in particular through the SPS Agreement[108] and TBT Agreement.[109] The **SPS Agreement** applies particularly to GM foods as is shown by the WTO Panel in the Biotech Products case which considered the de facto-moratorium adopted by the EU and halting the marketing approval of GM products an infringement of the SPS Agreement.[110] The restrictions were considered not to be based upon a sufficiently thorough risk assessment (despite the EU attempting to avail of Art. 5.7 of the SPS Agreement and precautionary principle in their arguments). The **TBT Agreement** will also be relevant in relation to labelling amongst other issues and again any measures must be proportional.[111]

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[103] See Makatsch (n. 100), pp. 218 ff.; Rudolf Streinz, Rechtliche Aspekte, in: Dieter Sturma/Dirk Lanzerath/Bert Heinrichs (eds.), Gentechnik in der Lebensmittelproduktion. Naturwissenschaftliche, rechtliche und ethische Aspekte (2011), pp. 57, 84.

[104] Cartagena Protocol on Biosafety to the Convention on Biological Diversity adopted on January 29. See the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (NKP).

[105] See Errass, pp. 185 ff. (n. 96).

[106] See for instance Ruth Mackenzie/Françoise Burhenne-Guilmin/Antonio G.M. La Viña/Jacob D. Werksman, An explanatory Guide to the Cartagena Protocol on Biosafty, IUCN Environmental Policy and Law Paper No. 46 (2003), pp. 63 ff.; Martin Scheyli, Das Cartagena-Protokoll über die biologische Sicherheit zur Biodiversitätskonvention, ZaöRV (2000), pp. 771 ff., 785 ff.; Katja Loosen, Das Biosafety-Protokoll von Cartagena zwischen Umweltvölkerrecht und Welthandelsrecht (2005), pp. 6 ff.

[107] N. 104.

[108] Agreement on the Application of Sanitary and Phytosanitary Measures.

[109] Agreement on Technical Barriers to Trade.

[110] WTO Panel Report European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 8.13 ff.

[111] For more details on the TBT Agreement, see Report Italy, pp. 226 ff.

In addition, the **General Agreement on Tariffs and Trade 1994 (GATT)**[112] must be taken into account. This raises the question of whether GMOs are equivalent to non-GM products in accordance with Art. III of the GATT. This question raises a controversy that has not yet been answered.[113] Restrictions of certain GM products also fall under the SPS and TBT Agreement. In addition, it is likely that labelling schemes also have to comply with WTO law. On the whole, it must be considered that there are potential conflicts between the Cartagena Protocol and international trade laws. Both agreements are of equal validity, thus a balance of interests must be found.[114]

Additionally, the fundamental customary law rules and several soft law **principles** of international environmental law are to be stressed, specifically with regard to GMOs, e.g. for the principle of sustainable development, the precautionary principle, the polluter-pays-principle and the source principle as well as the concepts of common concern of humankind and common heritage of humankind.[115]

EU Law

As to the EU and its Member States, the **Charter of Fundamental Rights of the European Union (ChFR)**[116] has to be taken into account. In context with the duty to protect individuals from environmental and health risks – thus including risks associated with the use of GMOs – the Charter provisions on right to life,[117] the right to respect an individual's physical integrity,[118] the freedom to conduct a business[119] and the right to property[120] must be taken into account.[121] In addition, the Charter aims at ensuring both a high level of human health[122] and environmental protection[123] as well as a high level of consumer protection.[124] The EU also has the competence – conferred by the **Treaty on the Functioning of the European Union**

[112] General Agreement on Tariffs and Trade 1994, April 15, 1994.

[113] See Report Switzerland, p. 269.

[114] Thereto Jan Neumann, Die Koordination des WTO-Rechts mit anderen völkerrechtlichen Ordnungen (1994), pp. 112 ff., in particular pp. 250 ff.

[115] Report Germany, p. 87.

[116] Charter of Fundamental Rights of the European Union (OJ C 303, 14.12.2007, p. 1).

[117] Art. 2(1) ChFR.

[118] Art. 3(1) ChFR.

[119] Art. 16 ChFR.

[120] Art. 17 ChFR.

[121] Report Germany, pp. 87 f.

[122] Art. 35(2) ChFR.

[123] Art. 37 ChFR.

[124] Art. 38 ChFR.

(TFEU) – to legislate on the contained use of GMOs,[125] on the release into the environment and placing on the market of GM food[126] and on consumer protection.[127]

In the field of both genetic engineering law as well as food law, the regulations of the Member States are to a large extent dictated by the EU regulatory framework for GMOs.[128]

The general **legal framework for genetic engineering**, i.e. for the creation and any uses of GMOs, is composed of Directive 2009/41/EC,[129] Directive 2001/18/EC,[130] Regulation (EC) No. 1830/2003,[131] and Regulation (EC) No. 1946/2003.[132] The latter EU regulation implements the Cartagena Protocol. These directives and regulations are complemented by numerous regulations and decisions as well as (non-binding) recommendations.[133] The evolution of this legal regime shows a shift of focus from boosting new technologies that would have the potential to improve competitiveness and employment towards an approach that reflects the reactions of consumers who are unsure whether GM products are safe.[134]

For the time being, the last step was the proposal by the European Commission in 2010 for a regulation amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.[135] Thereby, the Commission tackles the impasse head on and for the first time raises the discussion whether the cultivation of GMOs should be re-nationalised.[136] The Commission does not question the authorisation procedure, nonetheless it leaves the

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[125] Art. 192(2) TFEU.

[126] Art. 114(1)(2) TFEU.

[127] Art. 169(2) TFEU.

[128] Cf. also Streinz, p. 58 (n. 103).

[129] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).

[130] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

[131] Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

[132] Regulation (EC) No. 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

[133] See Matthias Herdegen/Hans-Georg Dederer, Internationales Biotechnologierecht, EU-Recht/Regelungen (Stand 2012).

[134] About the three stages in the evolution of EU policy on GMOs see Report Italy, pp. 218 f.

[135] Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, COM(2010) 375 final, 13 July 2010.

See the current Progress Report, Council of the EU, 2010/0208 (COD), Brussels, 3 June 2012, available at: http://register.consilium.europa.eu/pdf/en/12/st10/st10883-re01.en12.pdf at 5.

[136] See Mary Dobbs, Legalising General Prohibitions on Cultivation of Genetically Modified Organisms (2010), 11 German Law Journal 1347; José Martinez, Grenzen einer Renationalisierung des Agrarbinnenmarktes. Zum Vorschlag der Kommission zur Änderung der

definition of reasons on which conditions the cultivation of GM plants is to be banned up to the Member States' discretion. Henceforth, according to the new Art. 26b Directive 2001/18/EC, the Member States are free to decide whether they want to restrict or prohibit the cultivation of GMOs even based on other grounds than those related to the assessment of potentially adverse effects on health and environment.[137] Art. 26b does not define those other grounds, in its communication to the European Parliament, however, the Commission enumerates the reasons for the proposed modification of the existing legislative framework.[138] The reasons include the protection of a small-scale structured agriculture, organic farming, consumer protection or the lack of public acceptance of genetic engineering. The proposed legislative changes have prompted differing reactions in the Member States. While some countries like Austria support the amendments because they see themselves confirmed in their traditionally restrictive policy they already follow on a national level, most of the other Member States oppose to such a gateway for national initiatives and particularities. The proposal is also of relevance for the "GMO-free zones" and will be discussed below (section "Subsidies for a GMO-free production").

As far as general food law is of interest in the present context, the general **legal framework for food** is made up of Regulation (EC) No. 178/2002,[139] Regulation (EC) No. 834/2007[140] and Directive 2000/13/EC.[141] The report will not go into more

EU-Freisetzungsrichtlinie, in: Roland Norer/Gottfried Holzer (eds.), Agrarrecht Jahrbuch 2011 (2011), pp. 152 f.

[137] Consequently, if the proposed amendment is eventually passed and if the Member States wish to avail of it, they will have to identify a relevant objective justification that makes a national or regional prohibition proportionate. One such objective justification could be that of public morality, which is an acceptable justification within WTO law also (Art. XX of GATT); it would avoid the SPS Agreement being raised and the treatment of this justification may be sufficiently flexible to allow prohibitions to be accepted by the Dispute Panel and Appellate Board as proportionate; Report Ireland, pp. 191 ff.

[138] Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the freedom for Member States to decide on the cultivation of genetically modified crops, COM(2010) 380 final.

[139] Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

[140] Council Regulation (EC) No. 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No. 2092/91 (OJ L 189, 20.7.2007, p. 1).

[141] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). This Directive will expire on 13 December 2014 and will be substituted by Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004 (OJ L 304, 22.11.2011, p. 18).

detail as to the contents of these general provisions unless there is cause in context with genetic engineering, our matter at hand.

The **legal framework for GM food**, i.e. GMOs for food use, food containing or consisting of GMOs, or food produced from or containing ingredients produced from GMOs (hereinafter: GM food),[142] is set by Regulation (EC) No. 1829/2003.[143] The overall purpose of this EU legal framework for GM food is to "ensur[e] a high level of protection of human life and health, … environment and consumer interests …, whilst ensuring the effective functioning of the internal market".[144] One of the main pillars to reach this goal are provisions installing a thorough pre-marketing safety assessment of GM food as well as transparent labelling requirements enabling consumers to make an informed choice. Strict post-marketing measures including monitoring and continuous traceability of GM food complete the picture. At the centre, Regulation (EC) No. 1829/2003 regulates the market authorisation and supervision of GM food as well as GM-specific labelling of GM food. Regulation (EC) No. 1830/2003[145] complements it with provisions governing the traceability of GM food "with the objectives of facilitating accurate labelling, monitoring the effects on the environment and … on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products".[146] The export of GM food to third countries requires the implementation of Regulation (EU) No. 1946/2003.[147] It transposes the Cartagena Protocol to EU law and introduces a common system of notification and information for transboundary movements of GMOs for direct use or for food processing.[148]

Systematically speaking, the legal framework concerning the use of GMOs in the EU might be looked upon as being anchored somehow in between general genetic engineering law and general food law. It refers, e.g., with regard to legal definitions,[149]

[142] Thus, it does not apply to food produced "with" GMOs. See Art. 3(1) Regulation (EC) No. 1829/2003 (n. 143).

[143] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

[144] Art. 1(a) Regulation (EC) No. 1829/2003 (n. 143). Concerning the change of the EU legislator's regulatory philosophy which was to ensure environmental and health protection at the beginning in 1990 but which has been extended to include consumer interest protection as well in 2001/2003, see Hans-Georg Dederer, Neues von der Gentechnik, ZLR 2005, pp. 308 ff.; Gernot Schubert, Paradigmenwechsel im Gentechnikrecht?, GenTechnik & Recht (2003), p. 53.

[145] N. 131.

[146] Art. 1 Regulation (EU) No. 1830/2003 (n. 131).

[147] N. 132.

[148] Art. 1 and 9–10 Regulation (EC) No. 1946/2003.

[149] See e.g. Art. 2(1) Regulation (EC) No. 1829/2003 (n. 143) referring to general food law for the purpose of the definitions of "food" and "feed"; Art. 2(5) referring to general genetic engineering law for the purpose of the definition of "GMO".

risk assessment[150] or safeguard measures,[151] to general genetic engineering law as well as to general food law.[152]

As to the impact of EU law in **Non-Member States**, the case of Switzerland is a remarkable example, especially considering its partial integration via countless bilateral treaties concluded with the EU. In the end, both legal regimes are equivalent, if not identical, in relation to genetically modified food. In many cases, Swiss law refers to or incorporates European law without mentioning it specifically.[153] The legal effect of the Agreement on Agriculture I[154] and II[155] is limited because these two treaties do not concern GMOs directly.

Another example is Norway, which, as a member of the EEA, is required to adopt much of the EU legislation. Nonetheless, EU regulations on genetically modified food and feed, among them Regulation (EC) No. 1829/2003 and Regulation (EC) No. 1830/2003, are still not implemented in Norway.[156] Until implementation of these regulations, Norway has national legislation concerning processed GM food and feed products that are harmonised with the EU legislation.[157]

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[150] See e.g. Art. 5(5)(a) Regulation (EC) No. 1829/2003 (n. 143) referring to general genetic engineering law.

[151] See Art. 34 Regulation (EC) No. 1829/2003 (n. 143) referring to general food law.

[152] Report Germany, p. 92, concludes that the regulatory framework for GM food seems to rest on the two pillars genetic engineering law and food law. Nevertheless, from a systematic point of view, GM-food law has to be regarded as being part of genetic engineering law. This holds true all the more as both Regulation (EC) No. 1830/2003 (e.g. Art. 5) (n. 131) and Regulation (EC) No. 1946/2003 (e.g. Art. 9–10) (n. 132), which belong to the general legal framework for GMOs, also refer to particular regulatory aspects of GM food.

[153] Art. 16(2) and Art. 17(6) GTA for example that apply in particular to food refer on the international recommendations and foreign trade relations, meaning according to the parliamentarian debate the EU law; Report Switzerland, p. 270. In general see Roland Norer, Europäisierung des Schweizer Agrarrechts. Zwischen Bilateralen Abkommen und autonomem Nachvollzug, in: Festschrift Richli (2011), pp. 569 ff.

[154] Agreement between the European Community and the Swiss Confederation of in trade with agricultural products (OJ L 114, 30.4.2002, p. 132; SR 0.916.026.81).

Thereto Richard Senti, Abkommen über den Handel mit landwirtschaftlichen Erzeugnissen, in: Daniel Thürer/Rolf H. Weber/Wolfgang Portmann/Andreas Kellerhals (eds.), Bilaterale Verträge I & II Schweiz – EU. Ein Handbuch (2007), pp. 731 ff.

[155] Agreement between the European Community and the Swiss Confederation amending the Agreement between the European Economic Community and the Swiss Confederation of 22 July 1972 as regards the provisions applicable to processed agricultural products (OJ L 23, 26.1.2005, p. 17; SR 0.916.026.82).

Thereto Richard Senti, Abkommen über landwirtschaftliche Verarbeitungserzeugnisse, in: Daniel Thürer/Rolf H. Weber/Wolfgang Portmann/Andreas Kellerhals (eds.), Bilaterale Verträge I & II Schweiz – EU. Ein Handbuch (2007), pp. 789 ff.

[156] For the reasons see Report Norway, pp. 247 f.

[157] Nevertheless, the Norwegian EEA Agreement Annex XX (Environment) Art. 25.d(c) gives a basis not to approve living GMOs in Norway that have been approved in the EU.

National Law

Constitutional Foundation

According to all the submitted national reports, only Switzerland has a constitutional provision on GMOs and food. The Federal Constitution of **Switzerland** (FC)[158] enshrines in Art. 120 a specific provision on non-human gene technology.[159] According to Art. 120(1) FC, human beings and their environment shall be protected against the misuse of gene technology. Only abuse, i.e. only "excrescence of genetic engineering"[160] is banned. Art. 120(2) FC provides the following criteria which have to be taken into account: the dignity of living beings, the safety of human beings, animals and the environment, as well as the protection of the genetic diversity of animal and plant species.[161] In addition, in this context, Art. 118(2)(a) FC as basis for the Confederation to legislate on the use of foodstuffs that may be dangerous to health and Art. 74 FC about protection of the environment as basis for regulations to protect against indirect damage, including damage through foodstuffs, are further legal bases to be taken into account.[162]

In this context, the new *Hungarian* Constitution dating from 2011 must also be mentioned: its Art. XX(2) states that Hungary shall promote the effective application of the right to physical and mental health by, among others, "an agriculture free of genetically modified organisms". This provision closed a long debate and in the end defines the whole country as a GM-free zone.[163] The question of compatibility with EU law is of course raised immediately in this context.

All other national reports cite general fundamental rights such as the right to life or health, whose aspects can – in the broadest sense – be linked with food safety and genetic technology.[164]

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[158] Federal Constitution of the Swiss Confederation of 18 April 1999 (SR 101).

[159] As to the history of its legislatory evolution see Report Switzerland, p. 261.

[160] German: "Auswüchse der Gentechnologie"; see Report Switzerland, p. 263.

[161] See Christoph Errass, Öffentliches Recht der Gentechnologie im Ausserhumanbereich (2006), pp. 59 ff.; Christoph Errass, 20 Jahre Würde der Kreatur, ZBJV 2013, pp. 187 ff. Cf. Also Astrid Epiney/Bernhard Waldmann/Magnus Oeschger/Jennifer Heuck, Die Ausscheidung von gentechnikfreien Gebieten in der Schweiz de lege lata et de lege ferenda. Unter besonderer Berücksichtigung der Rechtslage in der EU (2011), pp. 73 ff.

[162] Report Switzerland, p. 265.

[163] Anikó Raisz/János Ede Szilágyi, Report Hungary, in: Paul Richli (ed.), L'agriculture et les exigences du développement durable. XXVIe Congrès et Colloque Européen de Droit Rural, Bucarest, 21–24 septembre 2011 (2013), pp. 545 f.

[164] See e.g. Report Canada, p. 343; Report Germany, pp. 83 ff.; Report Ireland, pp. 175 f.; Report Taiwan, pp. 392 f. In Finland the Constitution has enacted a provision on environmental liability; Report Finland, p. 157.

Statutory Law

The national statutory law in the analysed states has many different points of contact to the legal order, e.g. environmental protection, nature conservation,[165] agricultural or aquaculture[166] policy or product standards.[167] Furthermore, in some states the relevant law is not only enacted on federal level, but also by regional entities.[168] The competences are multifaceted and differ from state to state.

In the present case, the implementation of EU law makes clear that it must be distinguished between **genetic engineering law** and general **food law**, as the example of Germany illustrates.[169] Provisions on GM food tend to be found in regulation on genetic engineering law rather than in general food law.[170] This is also the case in Switzerland. The relevant Swiss statutory law is based on the Foodstuff Act (FSA) on the one hand and on the Gene Technology Act (GTA) on the other.[171] Foodstuffs are subject to both regulations, but foodstuffs with GMOs are generally regulated in the GTA and its provisions are implemented in several ordinances.

Regarding the link between genetic technology and food security, the steadily increasing creation of specific **Agencies** might be interpreted as an attempt at overcoming the fragmentation of competences.[172]

By way of example, in Belgium it is impossible to regulate the whole issue in one piece of legislation applicable for the whole country due to the various competences within the state and its federal entities. Thus, a combination of a cooperation agreement between federal and regional authorities on the one hand, and federal and regional acts and regulations on the other constitute a balance between the claims of those entities.[173] The decisions made by different administrative bodies are based on a common scientific evaluation system comprising the Biosafety Advisory Council (BAC) and the Biosafety and Biotechnology Unit (SBB). The deliberate release of GMOs in the environment and the placing on the market of all GMOs and GMOs-based products fall under the scope of the BAC; the SBB governs the contained use activities with GMOs and pathogens.[174]

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[165] See Report Norway, p. 253, where the Nature Diversity Act 2009 regulates also the benefits arising out of the utilisation of genetic material.

[166] See Report Norway, p. 252, about genetic modified fish in the Aquaculture Act 2005.

[167] See Report Belgium, pp. 129 f.

[168] E.g. Report Belgium, p. 130; Report Germany, p. 85.

[169] Report Germany, pp. 85 ff.; cf. also Report Ireland, pp. 179 f.

[170] German EC Genetic Engineering Implementation Law (EG-Gentechnik-Durchführungsgesetz, EGGenTDurchfG), BGBl. 2004 I p. 1244.

[171] Federal Act on Non-Human Gene Technology (Gene Technology Act, GTA) of 21 March 2003 (SR 814.91); Report Switzerland, pp. 273 ff.

[172] See also Report Canada, pp. 345 f.; Environmental Protection Agency in Ireland, Report Ireland, p. 184.

[173] Cf. Report Belgium, p. 131.

[174] Report Belgium, p. 131.

The situation looks similar in Germany, where the federal government may establish federal agencies implementing and enforcing federal food laws, but in general, the relevant federal law is executed by the Länder. As to genetic engineering law, the federal legislator has exhausted its competence in this field.[175]

In Macau SAR, the previous regulatory framework governing food safety was divided between several Departments in the sense of shared competences. To overcome such fragmentation with the new Macau Food Safety Law (MFSL), a centre for food safety was established.[176] Nevertheless, the legal regime governing the issue of food safety remains fragmented.

In the USA, under the 1986 Coordinated Framework for Regulation of Biotechnology[177] three different administrative agencies have regulatory authority: "[T]he US Department of Agriculture (USDA) ensures that GMOs are safe to grow; the US Environmental Protection Agency (EPA) ensures that they are safe for the environment; the US Food and Drug Administration (FDA, along with the EPA) ensures that they are safe to eat."[178] For our main issue at hand, the FDA is the most relevant. "Its policy relies in part on the concept of substantial equivalence".[179] "The FDA requires premarket review only for foods that lack substantial equivalence – foods with characteristics that carry higher risk (e.g. toxin levels or a new substance);" the authority makes use of instruments like guidance documents, which are less formal than regulations and "do not legally bind the FDA or the public".[180]

Principles

Alongside the public law regulating the use of GMOs for food production, legal principles permeate the relevant legislation. On a European level namely, the principles of prevention, precaution and proportionality are fundamental principles within the EU, as supported by their presence in the Treaty on the Functioning of the EU (TFEU) and in the case-law of the Court of Justice of the EU.[181] Furthermore,

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[175] Report Germany, p. 88.

[176] Report Macau SAR, pp. 431 f.

[177] Report USA, p. 309, citing Office of Science and Technology Policy (OSTP), Coordinated Framework for Regulation of Biotechnology Products, 51 Fed. Reg. 23,302 (June 26, 1986) (drafted in cooperation with administrative agencies).

[178] Report USA, p. 309.

[179] Report USA, p. 313, stating that a "GM food product is considered substantially equivalent to its conventional counterpart if their nutritional components do not differ".

[180] Report USA, p. 315, citing Erica Seiguer/John J. Smith, Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances, 60 Food & Drug L.J. 17, 20 (2005).

[181] E.g. Art. 191 TFEU contains prevention and precaution in relation to the environment (but with mention of health and Art. 11 requires environmental protection components to be integrated across EU law); Case T-147/00 Laboratoires Servier v Commission [2003] ECR II-85, para 52; Joined Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00, & T-141/00, Artegodan GmbH v. Commission [2002] ECR 11–4945, para 184; and Case C-132/03 Ministero della Salute v Coordinamento delle Associazioni per la Difesa dell'Ambiente e dei Diritti degli

although the TFEU emphasises the role of prevention and precaution in relation to environmental protection, Regulation (EC) No. 178/2002 (the General Food Law)[182] clearly applies all three principles in the context of food and feed regarding threats to health.[183]

Most of the national legislations refer to the **precautionary principle** in context of environmental protection,[184] in rare cases however also explicitly with reference to genetic engineering. The Belgian Royal Decree of 21 February 2005 regulating the deliberate release into the environment and placing on the market of GMOs as or in products (Art. 1) for instance formulates the objective of the Decree as "in accordance with the precautionary principle", to protect human health and the environment when carrying out the activities covered by the Directive 2001/18/EC and the Decree. Consequently, the deliberate release of GMOs and placing on the market of GMOs as or in products are subject to an authorisation of the competent federal ministers (Art. 3 and 4). After filing a notification as well as an environmental risk assessment fulfilling all requirements with regard to contents specified in Annex II, such an authorisation may be granted. Said Annex refers to the precautionary principle.[185]

Having outlined the general legal framework and the pertinent principles regulating the use of GMOs for food production on international, regional and national level, the following paragraphs on market admission (section "Admission to the market"), labelling (section "Labelling") and liability (section "Liability") shed light on the concrete content of said legislation in those three areas. They will be examined more closely on the basis of the national reports.

Admission to the Market

Various states have adopted measures governing the conditions to be met before a GM product can be placed on the market. They range from restrictions (section "Restriction of GMOs") at every stage of the production chain to conditions

Utenti e dei Consumatori (Codacons) [2005] ECR I-416, para 35. Proportionality has long been accepted as a general principle of EU law: Case C-11/70 Internationale Handelsgesellschaft [1970] ECR 1125.

[182] Art. 7 Regulation (EC) No. 178/2002/EC (n. 139) deals with the precautionary principle directly, whilst prevention can be seen throughout the Regulation. Similarly, proportionality is reflected in various elements of the Regulation, including regarding the precautionary principle and in relation to national enforcement of the Regulation.

[183] See Report Ireland, p. 182.

[184] For example in Switzerland Art. 74(2) phrase 1 FC (n. 158); Art. 1(2) Federal Act on the Protection of the Environment (Environmental Protection Act, EPA) of 7 October 1983, SR 814.01.

[185] In his risk assessment, the notifier must ensure that an accurate assessment is made on a case-by-case basis of the potential adverse effects on human health and the environment, which may occur directly or indirectly. This assessment must be conducted according to the nature of the organism introduced, the intended use and the receiving environment; Report Belgium, pp. 132 f.

concerning coexistence (section "Coexistence") as well as the actual admission processes to be followed (section "Admission of GMOs") or threshold values to be observed (section "Threshold values"). The section concludes with elaborations on implementation, enforcement and the controlling regime (section "Implementation, enforcement, controlling regime").

Restriction of GMOs

The scepticism towards the use of GMO in food production is illustrated by various legal restrictions that genetic engineering faces. The most common instruments are prohibitions (section "Prohibitions"), moratoria (section "Moratoria"), safeguard clauses (section "Safeguard clauses"), subsidies for a GMO-free production (section "Subsidies for a GMO-free production") and "GMO-free zones" (section "GMO-free zones"). These restrictions are to be discussed in the following paragraphs.

Please note that not all states restrict the use of GMO.[186] In Canada for instance, apart from the risk assessment carried on by the Canadian regulator, there are **no** such legal **restrictions** to the dissemination of GMO on one's land.[187] As farming practices remain linked to property,[188] any debate remains within the private sphere and does not trigger public interest legislation. Hence, whenever farming practices abide to provincial and federal agri-laws and regulations (zoning, etc.), no other impediment will restrict a farmer's property right to exploit his fields as he pleases, be it traditional or GMO. Nevertheless, some voluntary actions were taken, admittedly at a more local level. Indeed, the only impediment to farming by using GMOs remains the absence of proper authorisation by the Canadian regulator.

Similarly, in the USA, relatively few restrictions – in comparison with the EU – "limit the use of approved GMOs for the production of food and feed". Federal law allows producers to cultivate GM varieties under the condition that they were approved by the authorities (nonregulated status). On contractual basis, seed manufacturers often insist on contractual obligations. Thus they may require the farmer "to plant a 'refuge' area of non GM plants".[189] The approval of GM food varieties also signifies that "they can be sold or processed as food and feed." What

[186] See above section "Position of the government on GMOs." See e.g. Report Macau SAR, pp. 434 f., where the law – focussed on the commercialisation or the import of foodstuff – contains no specific references to GMOs. Report Taiwan, p. 397, where there is no general prohibition of GMOs, but restrictions exist in form of certain rules for the approval of GMO research and development initiatives.

[187] Report Canada, p. 345.

[188] See the Schmeiser case (Monsanto Canada Inc. v. Schmeiser [2004] 1 S.C.R. 902); for details see Report Canada, pp. 351 ff.

[189] Report USA, pp. 316 f.: "To protect intellectual property, seed developers prohibit saving and replanting seeds. Bowman v. Monsanto Co., 569 U.S. __, 133 S. Ct. 1761 (2013) (without permission of the patent holder, a farmer cannot reproduce patented seeds by planting and harvesting)."

is more, state laws generally support GM technology. The US Report mentions the possibility to create criminal penalties or impose statutory damages for destruction of GM research or field crops or pre-empt local government prohibitions of GM cultivation.[190] There are a few state laws in which the use of biotechnology is restricted in organic production, those states thus follow the example of the federal law when it comes to provisions for organic products.[191] Further and more extensive restrictions do exist, but only in a few states. In reaction to some unapproved GM varieties that have been discovered in farm fields and in the food chain, some states have enacted laws that govern the production of crops (California, Arkansas, Missouri).[192]

Prohibitions

Over the past, individual states have repeatedly prohibited specific admissions of GM products on their territory, sometimes even against an admission issued according to EU law, thus accepting a conflict between national and EU law. Of such nature are the cases that often led to recourses to the European Court of Justice (ECJ) or even to WTO-Panels. Generally, national prohibitions are only permitted by EU and WTO law in accordance with their regulation, e.g. through the operation of a safeguard clause in situations where there is a risk to the environment or human health.

In context with the EU law, this situation is illustrated very well by the case of *Italy*, where the Government addressed the concerns of its citizens both in 2000 and in 2013.[193]

In 2000, a Prime Minister's decree suspended, on a cautionary basis, the marketing and utilisation of three transgenic maize products of the Monsanto Company that had previously been authorised by the European Commission's decisions dated 98/292 and 98/294.[194] It was unclear whether GM maize was to be considered "substantially equivalent" to existing food products or ingredients and whether foodstuffs containing said GM maize could therefore be introduced to the market.[195]

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[190] Report USA, p. 317.

[191] Report USA, p. 317, citing the example of Michigan Organic Products Act of 2000, Mich. Comp. Laws § 286.907(d) (excluding use of GM organisms from definition of organic agriculture).

[192] In detail see Report USA, pp. 317 ff.

[193] Report Italy, p. 221.

[194] Commission Decision No. 98/292/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line Bt-11), pursuant to Council Directive 90/220/EEC (Text with EEA relevance) (OJ L 131, 5.5.1998, p. 28) and Commission Decision No. 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON 810), pursuant to Council Directive 90/220/EEC (Text with EEA relevance) (OJ L 131, 5.5.1998, p. 32).

[195] Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 043, 14.2.1997, p. 1) established that in the case of novel foods held to be equivalent to traditional products, the procedure to be followed

Monsanto, who brought the case against the Italian Government before the Regional Administrative Court, argued that the decree was not compatible with Community law. The verdict issued by the Court of Justice in September 2003 (case C-236/01)[196] corroborated the argumentation that the concept of substantial equivalence does not exclude the hypothesis that new foodstuffs may be considered as substantially equivalent to existing foodstuffs even if "they present differences in composition which are devoid of effects on public health" as the most likely interpretation of the relevant Community law.

In 2013, the Italian Ministry of Health, jointly with the Ministry of Agriculture and the Minister of the Environment, issued a ban valid throughout Italy on cultivation of MON810 maize varieties deriving from genetically modified seed "until Community measures are adopted as detailed in Art. 54, section 3, of Regulation 178/2002 and in any case for no longer than 18 months after the date of the decree". Therefore it should be noted that Sentence C-58/10, dated 8 September 2011, Monsanto v. Ministre de l'Agriculture et de la Pêche, issued by the Court of Justice,[197] stated that the Member States cannot suspend or forbid the utilisation or marketing of GMOs if the GMOs in question have been authorised pursuant to Regulation (EC) No. 1829/2003, unless the conditions specified in Art. 34 hold. The latter Article states that in the presence of new elements, any Member State can adopt emergency measures with regard to the use of GMOs that have already been authorised, by setting in motion the procedure indicated in Art. 53 Regulation (EC) No. 178/2002. Now, with reference to the maize variety MON810, the Italian government felt a duty to intervene in a cautionary manner in order to protect the environment and the biodiversity of its own territory.

In relation to WTO law, the former "moratorium" laid down by EU law must be mentioned.[198] In October 1998, a few Member States who viewed GMOs very critically succeeded in establishing a moratorium for new GMOs. France, Italy, Greece, Denmark, Luxemburg and Austria had blocked new admissions of GMOs in the competent committee, e.g. by calling on the safeguard clause in order to temporarily prevent that GM maize and canola be put into circulation. This moratorium was then subject of an action before the WTO brought forward in 2003 by some trading partners of the EU, especially the USA, Argentina and Canada. The arbitration body of the WTO, the panel, stated in its report in 2006 that from 1999 to 2003, the EU had applied a de facto moratorium for the admission of GMOs. In doing so, this had

was the "simplified" version that required only a simple communication to the Commission by the importing company.

[196] Case C-236/01 Monsanto Agricoltura Italia SpA and Others v. Presidenza del Consiglio dei Ministri and Others [2003] ECR I-08105.

[197] Case C-58/10 Monsanto SAS and Others v. Ministre de l'Agriculture et de la Pêche [2011] ECR I-07763.

[198] For further information see Matthias Herdegen/Hans-Georg Dederer, (n. 133), 2. Richtlinie 2001/18/EG, para. 1 (2010); Daniela Nowotny, pp. 393 f (n. 26).

led to inappropriate delays that were not in accordance with the SPS Agreement.[199] Additionally, the Panel considered that national regulations banning GM plants based on reasons that were not justified by scientifically proved safety deficiencies constituted an illegitimate obstacle to trade and were therefore an inadmissible violation of the SPS Agreement. The EU obliged to implement the Panel's findings within the negotiated delay. First, the national bans based on safeguard clauses had to be repealed. This proved to be a tedious matter since the Commission did, in many cases, not dispose over the necessary majorities during the comitology procedures, neither in the regulatory committee nor in the Council. Its hands were tied concerning the decision to re-install conformity with WTO law by waiving the bans based on the national safeguard clauses as a whole and in a timely manner. Yet the EU reacted to the political will of its Member States by tightening its legislation accordingly. Stricter requirements concerning the placing on the market, labelling and traceability of GMOs were adopted,[200] which eventually led to the abolishment of the moratorium in 2004.[201]

The attempts of introducing national prohibitions have been undertaken on a regular basis and every so often, the European Commission's exertion to invalidate the prohibitions in order to reinstate the legal framework failed as a result of blocking minorities in the European Council.[202]

Moratoria

Currently, official moratoria exist neither on the EU level nor on the domestic level. As discussed above, the **EU** moratorium for market authorisations of GMOs, which was adopted by the ministers for the environment of the EU Member States for the duration of 1998–2004, consisted in Community authorities not answering to the authorisation requests submitted by foreign multinationals that wished to market their GM seed in Europe. This attitude of omission led to a de facto moratorium, although one lacking a legal basis as the WTO Panel confirmed.

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[199] WTO, Reports of the Panel, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291, WT/DS292, and WT/DS293 (September 29, 2006). In detail Report Italy, pp. 228 ff.; Lorenz Stökl, Der welthandelsrechtliche Gentechnikkonflikt. Die europarechtlichen Handelsbeschränkungen für gentechnisch veränderte Lebensmittel und ihre Vereinbarkeit mit Welthandelsrecht (2003).

[200] The Regulations (EC) No. 1829/2003 (n. 143), No. 1830/2003 (n. 131) and No. 1946/2003 (n. 132) were passed forming henceforward the revised legal framework for a stricter regulation of GMOs (together with Directive 2001/18/EC adopted earlier in 2001).

[201] The first GM product approval was issued again in May 2004; see Commission Decision 2004/657/EC of 19 May 2004 authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 300, 25.9.2004, p. 48).

[202] See also section "Safeguard clauses" below.

General moratoria in this tradition are no longer part of the EU-Member States' strategies since they are no longer considered constructive, especially since the respective WTO Panel. In order to control and restrict the use of GMOs, states recur to other measures. The following paragraphs describes a few of those instruments in more detail.

In contrast, a "real" moratorium, that is to say de jure, is integral part of the Swiss law.[203] In 2004 a popular initiative was launched, the so-called Moratorium Initiative, that was adopted on 27 November 2005 by the people and all cantons. Subsequently, the moratorium was enshrined in the constitution (Art. 197 Section 7 FC).[204] This moratorium ended on 27 November 2010, but was then extended on the legislative level twice (first to 27 November 2013, second to 31 December 2017) by amendments to Art. 37a Gene Technology Act (GTA).[205,206] Furthermore, the amendment of the Agriculture Act[207] commits the Federal Council to submit a report providing a methodology for the evaluation of the benefits of GM plants by 30 June 2016. Additionally, the Federal Council has to evaluate the advantages of genetically modified plants and present the results in a cost-benefit analysis (Art. 187d LAgr).

According to Art. 37a phrase 1 GTA, no authorisation may be granted until 31 December 2017 for putting into circulation GM plants and parts of plants, GM seeds and other plant propagation material and GM animals for agricultural, horticultural or silvicultural purposes. Activities in contained systems and experimental field releases are permitted; research should not be hindered. GM foodstuffs derived from agricultural production are not allowed to be produced in Switzerland, but have to be imported, provided an authorisation for the putting into circulation of this

[203] In detail Report Switzerland, pp. 277.

[204] Report Switzerland, p. 261.

Cf. Art. 197 Section 7 BV Transitional Provision to Article 120 (Non-human gene technology) Swiss agriculture shall remain free of gene technology for a period of 5 years following the adoption of this constitutional provision. In particular, the following may neither be imported nor placed on the market:

(a) genetically modified plants that are capable of propagation, parts of plants and seeds that are intended for agricultural, horticultural or silvicultural use in the environment;
(b) genetically modified animals that are intended for the production of foodstuffs and other agricultural products

[205] Cf. Art. 37a GTA (n. 171) Transitional period for putting genetically modified organisms into circulation

No authorisations may be granted until 31 December 2017 for putting into circulation genetically modified plants and parts of plants, genetically modified seeds and other plant propagation material and genetically modified animals for agricultural, horticultural or silvicultural purposes. The Federal Council issues the required implementing provisions for this period.

[206] For further information cf. Rainer J. Schweizer/Isabelle Wildhaber/David Rechsteiner, Vorschläge für eine Schweizer Koexistenzordnung, in: Rainer J. Schweizer/Christoph Errass/Stefan Kohler, Koexistenz der Produktion mit und ohne gentechnisch veränderte Organismen in der Landwirtschaft – Rechtsvergleich sowie Grundlagen und Vorschläge für die knftige Regulierung in der Schweiz (2012), pp. 242 ff.

[207] Federal Law on Agriculture (LAgr) of 29 April 1998 (SR 910.1).

GM food exists. In the end, it remains unclear whether the moratorium is compatible with the provisions of the SPS Agreement.

Safeguard Clauses

WTO Law

In its Art. XX(b), the GATT-Agreement from 1947 sets forth the possibility to restrict the Agreement in context of the prohibition of GMOs by measures deemed necessary to protect human, animal or plant life or health. As the previous disputes on moratoria and non-admission of new GMOs as practiced by some EU-Member States has showed, the competent committee of the European Food Safety Authority (EFSA) did not consider that the safeguard clause enshrined in the EU law could justify moratoria. Thus, invoking Art. XX GATT is not likely to serve as legal basis for restrictions either.[208]

EU Law

EU law and, accordingly, domestic law provide for safeguard clauses. The main safeguard provisions within the EU are found with the TFEU, the GMO laws and Regulation (EC) No. 178/2002. The legislation provides for safeguard measures at the EU level also, but the ones examined in this article are those by Member States.

Applicable to all GMOs are Art. 114(4) and (5) **TFEU**, which stipulate the possibility of maintaining or introducing unilateral national measures. Art. 114(5) demands that Member States demonstrate "new scientific evidence relating to the protection of the environment or working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure". The provision does not mention and therefore excludes health protection. The criteria are cumulative, i.e. the evidence must (i) be new and scientific, (ii) relate to environmental protection or the working environment, (iii) be specific and (iv) arise after the harmonising measure's adoption. The two most difficult criteria to meet are those of newness and specificity.[209]

With regard to GM food, the legal framework for safeguard measures consists of Regulation (EC) No. 1829/2003 and Regulation (EC) No. 178/2002. Additionally, if the cultivation of GM food crops is addressed, Directive 2001/18/EC and the implementation of the according domestic legislation are pertinent.[210]

Emergency measures may be taken on the basis of Art. 34 **Regulation (EC) No. 1829/2003** under the condition of findings indicating that a GM food is likely to constitute a serious risk to human health or the environment or if, according to the

[208] Roland Norer, "Gentechnikfreie Zonen" in Österreich, RdU 5 (2006), pp. 188 f.

[209] Report Ireland, p. 186.

[210] See Report Germany, pp. 95 ff.

urgent opinion of the EFSA, a GM food authorisation is to be suspended or modified. For the relevant procedure in these emergency cases, it is to be referred to Art. 53 and 54 **Regulation (EC) No. 178/2002**. It follows that it is mainly the task of the European Commission to adopt the necessary emergency measures, e.g. the suspension of the sale of the GM food concerned.[211] Additionally, the Member States may adopt interim protective measures for the time being, that is to say as long as the Commission has not reacted on its own.[212]

Art. 23 **Directive 2001/18/EC** provides that Member States may provisionally restrict or prohibit the use or sale of a GM product, if "detailed grounds" support the conclusion that the GM product constitutes a risk to human health or the environment. These "detailed grounds" must be based on new or additional information or on new or additional scientific knowledge provoking the reassessment of existing information. It is, in general, the European Commission which will take the final decision on the respective Member State's safeguard measure in accordance with the so called comitology procedure.[213]

Also relevant to cultivation, Art. 18 **Directive 2002/53/EC**[214] provides for safeguard measures in relation to seeds. If it is established that the cultivation of a variety included in the common catalogue of varieties could in any Member State be harmful from the point of view of plant health to the cultivation of other varieties or species, or present a risk for the environment or for human health, that a Member State may upon application be authorised in the case of a genetically modified variety to prohibit the marketing of the seed or propagating material of that variety in all or part of its territory. Where there is imminent danger of the spread of harmful organisms or imminent danger for human health or for the environment, that prohibition may be imposed by the Member State concerned as soon as its application has been lodged until such time as a final decision has been taken. This provision is of more limited scope, but is relevant to human health and the environment and does not impose requirements regarding either newness or specificity.[215] This does not mean that the requirement that the threat be "established" or that there be "imminent danger" will be interpreted liberally however.[216]

All these provisions are usually interpreted conservatively, e.g. closely following the text due to the thorough risk assessment that is required beforehand.[217] The

[211] See e.g. Art. 53(1)(a)(i) Regulation (EC) No. 178/2002 (n. 139).

[212] See Art. 54(1)(1) Regulation (EC) No. 178/2002 (n. 139).

[213] See Art. 23(2) and 30(2) Directive 2001/18/EC (n. 130).

[214] Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 13.6.2002, p. 1). Art. 16(2) of the Directive also provides scope for unilateral national measures along the same lines as Art. 18.

[215] Report Ireland, p. 186.

[216] Cf. Commission Decision 2006/10/EC of 10 January 2006 concerning the provisional prohibition in Greece of the marketing of seeds of maize hybrids with the genetic modification MON 810 inscribed in the common catalogue of varieties of agricultural plant species, pursuant to Directive 2002/53/EC (OJ L 7, 10.1.2006, p. 27).

[217] Report Ireland, p. 187.

Member States have to put forward evidence that the level of protection is not satisfactory, which means they must disprove the outcome of the prior authorisation procedure and conditions imposed. Thus, although the application of Art. 18 Directive 2002/53/EC has been accepted,[218] this explains why the use of Art. 23 Directive 2001/18/EC has never been approved yet by EFSA or the Commission.[219] It is therefore difficult for the Member States to recur to safeguard clauses.[220]

According to the jurisdiction of the ECJ, the safeguard clauses are expression of the precautionary principle[221] and should therefore be interpreted in its light. Nevertheless, the safeguard clauses that specify "new" evidence have been interpreted as not being satisfied by a new interpretation of the data despite that such an interpretation may be logical in the context of the scientific uncertainty.[222]

Nonetheless, the safeguard clauses have been **invoked frequently** in order to repel GMOs:

In 2009 for instance,*Germany* invoked the safeguard clauses of Directive 2001/18/EC and the national GenTG (German Act on Genetic Engineering)[223] as well the safeguard clause of Regulation (EC) No. 1829/2003 with regard to MON810.[224] The safeguard measure ordered the temporary suspension of the French market authorisation for MON810 (Bt maize) as far as it concerns the cultivation of seeds of the GM variety MON810. This safeguard measure has been upheld by the national administrative courts. On the other hand, the Central Committee on Biological Safety (Zentrale Kommission für die Biologische Sicherheit – ZKBS) brusquely criticized the safeguard measure as being scientifi-

[218] Commission Decision 2006/335 of 8 May 2006 authorising the Republic of Poland to prohibit on its territory the use of 16 genetically modified varieties of maize with the genetic modification MON810 listed in the Common catalogue of varieties of agricultural plant species, pursuant to Council Directive 2002/53/EC (OJ L 124, 8.5.2006, p. 26).

[219] Nonetheless, the previous comitology procedure made the lifting of national prohibitions based on Art. 23 Directive 2001/18/EC impossible in practice for the Commission, as the Council were able to block proposals to lift the prohibitions. The Commission did succeed in lifting prohibitions relating to GM food and feed, as well as Greece's prohibition regarding seeds (Commission Decision No. 2006/10/EC of 10 January 2006 concerning the provisional prohibition in Greece of the marketing of seeds of maize hybrids with the genetic modification MON 810 inscribed in the common catalogue of varieties of agricultural plant species, pursuant to Directive 2002/53/EC (OJ L 7, 12.1.2006, p. 27)).

[220] E.g. Nicolas de Sadeleer, Procedures for Derogations from the Principle of Approximation of Laws under Article 95 EC, (2003) CMLRev 40, 889; Floor M. Fleurke, What Use for Article 95 (5)? An Analysis of Land Oberösterreich and Republic of Austria v Commission, (2008) 20 Journal of Environmental Law 267.

[221] Case C-6/99, Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others, [2000] ECR I-1651, para. 44.

[222] Joined Cases T-366/03 and T-235/04 Land Oberösterreich and Republic of Austria v Commission, [2005] ECR II-4005; Case C-121/07 Commission v France [2008] ECR I-9159; and the Opinion of Advocate General Mazák of 5 June 2008 in Case C-121/07 Commission v France at pt. 44.

[223] Sec. 20(2) GenTG, Gesetz zur Regelung der Gentechnik (BGBl. 1993 I p. 2066).

[224] Report Germany, pp. 96 f.

cally unfounded. Hence, a WTO Panel might well consider the safeguard measure a violation of the SPS Agreement.[225]

In the *Italian* case mentioned above (section "Prohibitions") about a Prime Minister's decree suspending, on a cautionary basis, the marketing and utilisation of three transgenic maize products of the Monsanto Company that had previously been authorised by the European Commission, the verdict issued by the Court of Justice reasoned in its sentence dated 9 September 2003, case C-236/01,[226] that every Member State could challenge the conclusion reached by the Commission, but only after carrying out the appropriate scientific verifications. Therefore, the Court of Justice stated that a Member State's power to make use of the safeguard clause detailed in Art. 114 of the Treaty (TFEU) is conditional on the prior undertaking, by the Member State in question, of an assessment of the risk, with reference to the precautionary principle. The Court therefore assigned the Italian referring court with the task of determining whether, in the particular case at hand, the investigation into the existence of a risk of a danger potentially harmful to human health had been carried out on the basis of the scientific knowledge available at the time of the assessment.

In *Austria* the Land of Upper Austria intended to ban GM crops throughout its territory by appealing to Art. 95.5 Treaty of Rome (actual Art. 114 TFEU). Upper Austria had submitted a draft bill of a ruling that would forbid the utilisation of biotechnology in agriculture to the Commission. The outcome, as everyone knows, is as follows: First the Commission, then the Court of First Instance[227] and then the Court of Justice[228] rejected the request for authorisation, because it had not been demonstrated that the territory of the Land of Upper Austria contained special or exceptional ecosystems which would have required a purpose-instituted risk assessment and which would thus have warranted the prohibition of GM crops. Also the justifications adduced pertaining to the limited surface area of farms in the Land in question and to their special vocation of organic farming had been rejected as insufficient.

National Law

While safeguard clauses play a prominent role in EU law, the national reports hardly hint at such provisions in national law, except for the measures of implementation of said EU law safeguard clauses.[229] Additional national safeguard clauses do not seem to exist, neither in EU Member States nor in any other country that is being examined in this report.

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[225] Cf. WTO Panel Report European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R, pp. 1037 ff. See also Hans-Georg Dederer, Die Nutzung der Gentechnik, in: Reinhard Hendler/Peter Marburger/Peter Reiff/Meinhard Schröder (eds.), Landwirtschaft und Umweltschutz (2007), p. 185.

[226] See n. 196.

[227] Case T-366/03 (n. 222).

[228] Joined Cases C-439/05 P and C-454/05 P Land Oberösterreich [2007] ECR I-7141.

[229] See for example in Germany: Sec. 20(2) GenTG, Report Germany, pp. 95 f.; Belgium: Art. 42 Royal Decree of 21 February 2005; Report Belgium, pp. 137 f.

Subsidies for a GMO-Free Production

According to the national reports, subsidies for the purpose of stimulating specifically GMO-free production are non-existent. Nevertheless, several benefit payments in agriculture may – at least indirectly – target GMO-free production.

Primarily, subsidies for **organic production** in the EU-Member States point to this direction,[230] since they indirectly offer an incentive to start or intensify GMO-free production because Regulation (EC) No. 834/2007[231] provides that the use of GMOs in organic production is prohibited.[232]

Another set of subsidies aiming at GMO-free production are the **agri-environment measures**, first introduced at the occasion of the CAP reform 1992 and actually based on Art. 28 Regulation (EC) No. 1305/2013.[233] The measures aim at encouraging farmers to preserve the environment and maintain the countryside on a voluntary basis by providing payments when they subscribe to the programme. Within the regulatory framework set by EU law, the Member States enjoy a wide margin of appreciation as to the implementation of the rural development programmes. The call for subsidising GMO-free agriculture and farming by binding promotional programmes to the condition of the renunciation of GMOs is not new, it has been raised regularly in the past.[234] In Austria for instance, linking agri-environment measures to the condition of GMO-free production would lead to a widely and extensively GMO-free agriculture since about 75 % of all agricultural holdings (covering a total of nearly 90 % of the agricultural surface in Austria) participate in these voluntary measures. On a federal level, this would de facto signify a voluntary abstention of the use of GMOs.

However, according to the European Commission's opinion, this path may not be treaded.[235] The Commission argues that making the eligibility for participation in agri-environment programmes dependant of using GMO-free seed could not be justified under ecological viewpoints, especially since the use of GM seed was deemed environmentally safe according to Directive 2001/18/EC. Furthermore, subsidies to farmers for the renunciation of the use GMO seed could not be granted since there was no respective benefit for the environment to compensate. The use of GM-free seed could therefore neither be required for participating in an agri-environmental programme nor be actively supported.

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[230] See Report Germany, p. 97.

[231] N. 140.

[232] Recital 30, Art. 4(a)(iii) and Art. 9 Regulation (EC) No. 834/2007 (n. 140).

[233] Regulation (EU) No. 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

[234] Roland Norer, pp. 194 f (n. 208).

[235] For details on a respective attempt in Slovenia, see the Commission report dating from 9 March 2006 „Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming", COM(2006)104 final, p. 5.

"GMO-Free Zones"

In states that tend to be more critical towards GMOs, the creation of so-called GMO-free zones can be noted especially on a local or regional level.[236] Entire districts or municipalities declare themselves GMO-free, advertising it on posters or the internet. Besides these voluntary measures, every so often there are attempts in national law to adopt binding provisions prescribing such zones.

Inventory

Both types of such zones, the voluntary as well as the legal measures, are mentioned in several national reports. On **European level** for instance, under the umbrella of the network "GMO-free Europe", currently 169 regions, 123 provinces, prefectures and departments plus 4713 local governments reaching from the Scottish Highlands over the whole continent to the Greek provinces joined forces.[237]

Within the EU, in *Belgium*, more precisely in the Walloon Region (and thus quite contrary to the Flemish Region), the Executive Order of the Walloon Government, implementing the Decree of 19 June 2008, provides for the possibility to establish GMO-free zones.[238] Such a zone consists of arable land of at least three farmers and covering at least 150 ha. The concerned farmers may submit a demand for the instauration of such a zone, and when approved, with limitations on GMO cultivation for adjacent land as a consequence. Apart from that, it has been suggested that 124 municipalities and the Walloon Region have declared themselves GMO-free. In January 2014, the region of Brussels proposed draft legislation that the around 260 ha of agricultural land in the Brussels region will be GMO-free, with reference to the costs of co-existence measures.

In *Germany* with regard to seed production, the Seed Commerce Law[239] provides that the Länder may set up so called "closed production areas".[240] Accordingly, e.g. Baden-Württemberg passed a Law for the Protection of Seed Production in Closed Production Areas[241] which provides for the establishment of closed production areas through statutory instruments. Such statutory instruments may define closed areas for the production of conventional or organic seed and, as a consequence, prohibit the cultivation of cross breeding GM crops.[242]

As far as it concerns natural conservation, GMOs may pose risks to fauna and flora or to ecosystems. Therefore, already the market authorisation may include

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[236] For examples see Roland Norer, p. 194 (n. 208).

[237] http://www.gmo-free-regions.org

[238] Report Belgium, p. 142.

[239] Saatgutverkehrsgesetz – SaatG, BGBl. 2004 I p. 1673.

[240] Sec. 29 SaatG (n. 239). Report Germany, p. 98.

[241] Gesetz zum Schutz der Erzeugung von Saatgut in geschlossenen Anbaugebieten (SaatErzG), GBl. 1969 p. 80.

[242] Cf. Sec. 1(1) and (2), 2(1)(1) SaatErzG (n. 241).

"conditions for the protection of particular ecosystems/environment and/or geographical areas".[243] Such areas ("zones") must be "GMO-free" with regard to the authorized GMOs only. Similarly, the cultivation of a GMO may be subject to an assessment of its impacts on a Natura 2000-site. If, according to this assessment, the cultivation of the respective GMO is likely to have significant adverse effects on those components which are decisive for the site's conservation objectives, the cultivation of the GMO is prohibited and must be banned.[244]

In addition, district and county councils have adopted resolutions calling for GMO-free agricultural production within their territory.[245] Of course, conventional and organic farmers may enter into agreements in which they commit themselves to GMO-free agriculture.

In *Ireland* some areas have declared themselves as GM-free.[246]

In *Italy* a number of Regions[247] had banned the cultivation of GM plants in certain areas of their respective territories; subsequently, some regions[248] banned GM crops throughout their territories by invoking the safeguard clause of Directive 2001/18/EC.[249] It is interesting to note that Sentence No. 183 dated 19 January 2010 issued by the Consiglio di Stato (i.e. the Italian Council of State), which recognised that the Decreto Legge 279/2004 was the outcome of the exclusive legislative competence of the State in matters pertaining to environmental protection, and the outcome of concurrent competence in questions pertaining to health, concluded with a ruling that required the "repeal, due to incompatibility, of the prohibitions and limitations introduced in some regional laws, pertaining to genetically modified crops." Therefore, according to the highest Italian administrative judge, the laws banning GM products passed by the Regions that had declared their territories to be GMO-free should not be applied.[250]

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[243] Art. 7(2) in connection with Art. 6(5)(e) Regulation (EU) No. 1829/2003 (n. 143). A similar provision is laid down in Art. 19(3)(c) Directive 2001/18/EC in connection with Sec. 16d(1)(3) GenTG (n. 223).

[244] Sec. 35(2) in connection with Sec. 34(1), (2) Nature Protection Act (Bundesnaturschutzgesetz, BNatSchG). Report Germany, pp. 98 f.; Hans-Georg Dederer, Gentechnikrecht, in: Ines Härtel (ed.), Handbuch des Fachanwalts Agrarrecht (2012), Kapitel 20, para 91 ff.; Christoph Palme/Jochen Schumacher, Die Regelungen zur FFH-Verträglichkeitsprüfung bei Freisetzung oder Inverkehrbringen von gentechnisch veränderten Organismen in § 34a BNatSchG, NuR 2007, p. 16.

[245] In Bavaria, more than 200 municipalities and counties have committed themselves to GMO-free agriculture on their territories. See http://www.stmuv.bayern.de/umwelt/gentechnik/index.htm, Report Germany, p. 99.

[246] Report Ireland, p. 193. Map and details of self-declared GM-free areas in Ireland in 2010: http://www.gmfreeireland.org/map/index.php

[247] For instance the Regions of Latium (with Law No. 53 dated 1 March 2000); Tuscany (with Law No. 53 dated 6 April 2000); Abruzzo (with Law No. 6 dated 16 March 2001); Umbria (with Law No. 21 dated 20 August 2001).

[248] The Regions of Marche (with Law No. 5 dated 3 March 2004) and Puglia (with Law No. 26 dated 4 December 2003).

[249] Report Italy, pp. 229 f.

[250] Report Italy, pp. 230 f.

The best known case within the EU is certainly *Austria*.[251] The draft for the Upper Austrian Act prohibiting Genetic Engineering 2002[252] stipulated a prohibition of GM plants and animals for the whole federal province of Upper Austria, provisionally for the duration of 3 years. The proposed legislation instructed the authorities to make the farmer remove his crop, if he cultivated GM seed or plants on his own land. The intention behind the draft was to protect organic farming as well as the traditional production of plants and animals from contamination (uncontrolled crossing of varieties) caused by GMOs. Biological diversity, in particular in sensitive ecological areas as well as the genetic resources in nature, including those in hunting and fishing, was to be protected from contamination by GMOs. After the notification to the Commission and the subsequent consultation with the EFSA, the Commission reached the conclusion that the draft was to be rejected since Austria did not provide any new data corroborating new scientific evidence for risks to human health and the environment.[253] The Court of First Instance dismissed the subsequent action,[254] the ECJ confirmed this decision.[255] After the attempt of introducing bans by installing GMO-free zones had clearly failed, the Upper Austrian legislator passed a so-called "Act on Genetic Engineering Precautionary Measures" as have other federal provinces.[256] These Acts usually allow the cultivation of GMOs under the condition that precautionary measures that are necessary and adequate for the avoidance of contamination of other land are taken. Possible measures are, according to the Acts, e.g. safety margins, buffer zones, pollen traps, appropriate crop rotation, specific sowing periods or the prevention of spread by agricultural machinery and equipment. In the end, the Commission did not oppose to these Acts encouraging precautionary measures since they cannot wholly prevent the cultivation of GMOs. Yet, the mere hindrance those precautionary measures constitute for the cultivation, the additional costs and time loss caused by the necessary procedures as well as the small-scale, diversified agriculture dictated by natural

[251] See Roland Norer, pp. 192 ff (n. 208).

[252] Oberösterreichisches Gentechnik-Verbotsgesetz, draft dating from 2002.

[253] Commission Decision No. 2003/653/EC of 2 September 2003 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty (OJ L 230, 16.9.2003, p. 34).

[254] Joined Cases T-366/03 und T-235/04 (n. 222). See Christoph Palme, Bans on the Use of Genetically Modified Organisms (GMOs) – the Case of Upper Austria, JEEPL 2006, p. 22; Christoph Palme, Das Urteil des Europäischen Gerichts zum oberösterreichischen Gentechnikverbotsgesetz, StoffR 2005, p. 222.

[255] Joined Cases C-439/05 P and C-454/2005 (n. 228).

[256] Gentechnik-Vorsorgegesetze. See also legislation in other federal provinces: Burgenländisches Gentechnik-VorsorgeG (LGBl 2005/64); Kärntner Gentechnik-VorsorgeG (LGBl 2005/5); Niederösterreichisches Gentechnik-Vorsorgegesetz (LGBl 6180–1); Oberösterreichisches Gentechnik-Vorsorgegesetz 2006 (LGBl 2006/79); Salzburger Gentechnik-VorsorgeG (LGBl 2004/75); Steiermärkisches Gentechnik-Vorsorgegesetz (LGBl 2006/97); Tiroler Gentechnik-Vorsorgegesetz (LGBl 2005/36); Vorarlberger Gesetz über Naturschutz und Landschaftsentwicklung (LGBl 1997/22); Wiener Gentechnik-Vorsorgegesetz (LGBl 2005/53).

physiogeographic conditions and landscape led to a certain reluctance of multinational companies to include Austria in their agri-economic strategies.[257]

As to an example **outside** the borders of the **EU**, in *Canada* some British-Columbia municipalities have passed resolutions declaring themselves GMO-free territories.[258]

In the *USA*, state measures authorise grower districts or administratively established seed production districts for the production of various GM plants. These districts are intended to "prevent commingling of industrial rapeseed (for oil or fuel production) and food varieties of rapeseed (canola)." In the end, the existence of such districts basically leads to a regional allocation of certain locally confined GM production hubs, which can, in other terms, be tantamount to GMO-free sectors or zones. Furthermore, the US law is no stranger to GMO-free zones, although only in the form of local bans. "Several California counties have banned the cultivation of GM crops within their borders. […] Efforts to enact bans in other California counties […] failed. After failure of the 2004 proposal to ban GMOs in San Luis Obispo County, farmers in the county negotiated a compromise: a system that allowed farmers who grew GM crops to give notice to others by marking a map, so that neighbo[u]ring farmers (organic and others) could take measures to protect their crop from contamination. A few individual towns have also banned, or tried to ban, the cultivation of GM crops."[259]

In *Mexico* the Law on Biosafety of Genetically Modified Organisms[260] specifies restricted zones.[261] Furthermore other regulations will also apply together with agreements on the designation of a protected area and precautionary measures. In Mexico, the restricted areas for the release of GMOs are (i) centres of origin or genetic diversity,[262] (ii) natural protected areas[263] and (iii) GMO-free zones.[264] Hence, Mexico disposes of a differentiated system of zones where the use of GMOs is subject to various restrictions.

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[257] Roland Norer, pp. 193 f. (n. 208).

[258] Report Canada, p. 345. See http://www.cban.ca/Resources/Topics/GE-Free-Zones

[259] All quotes in this paragraph are taken from the Report USA, p. 319.

[260] Art. 86–90 Law on Biosafety of Genetically Modified Organisms.

[261] Report Mexico, p. 377.

[262] In Centres of Origin and Genetic Diversity the release of GMOs is permitted when the GMOs intended to be released are distinct from native animal and plant species provided that these releases do not cause any negative effects on human health or biological diversity.

[263] In Natural Protected Areas activities with GMOs will only be permitted for remediation purposes in the cases that plagues or polluters could put at danger the existence of animal, aquatic or plant species and these GMOs where specifically created to avoid or combat that situation. However, activities with GMOs are banned in core areas of the Natural Protected Areas.

[264] GMO-free zones may be established for the protection of organic agricultural products and others of interest to the soliciting community. The zones will be established when GMOs of the same species to the ones resulting from production of organic agricultural products coincide, and when it is scientifically and technically demonstrated that their coexistence is not viable or that they would not comply with the normative requirements for their certification.

Due to the rather strict current moratorium, *Switzerland* is a GMO-free zone. The question remains whether GMO-free zones or zones reserved for the use of GMOs should be created when the moratorium runs out eventually without being prolonged for another period.[265] Switzerland is bound to find answers to this question, especially since Art. 7 GTA protects the production without GMOs and the freedom of choice. The legislator either has to agree on a definition of a GMO-free area and make sure it is in accordance with the Constitution, or the legislation needs to come up with a definition of areas adjacent to which no genetically modified organisms may be cultivated. From a legal point of view, both options are imaginable. Scientifically speaking however, the second option corresponds more easily with the typical Swiss geography with its small-scale structured topography. GMO-free zones would in any case probably be larger than areas in which GMOs could be cultivated. In any case, the creation of buffer zones is indispensable.

Legal Binding Force

The legal significance and content vary for each zone respectively: The **voluntary resolutions** are not legally binding.[266] They are mainly based on the decision of deliberately accepting possible economic losses in exchange of generating marketing advantages by abstaining from the use of these new technologies. Legally, such measures are to be considered voluntary commitments,[267] i.e. commitments by unilateral will declaring to strive for a specific goal. This certainly gives them effect in a public dimension, yet legally speaking they are not binding rather than mere unilateral declarations without obligation. The German Report however raises the question whether these resolutions are lawful because the municipalities or counties respectively might have acted ultra vires, i.e. beyond the limits of their competences which are restricted to matters of the local community.[268] It is likewise questionable whether a municipality may oblige farmers cultivating the municipality's real property to adhere to a clause laid down in their tenancy agreement providing for the use of GMO-free production methods.

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[265] Report Switzerland, p. 278. See ECNH, Opinion of 19 February 2013 (in German): Koexistenzregelung: Änderung des Bundesgesetzes über die Gentechnik im Ausserhumanbereich, GTG (Vernehmlassungsentwurf vom 30. Januar 2013) und Verordnung über Koexistenzmassnahmen beim Anbau von gentechnisch veränderten Pflanzen sowie beim Umgang mit daraus gewonnenem Erntegut, Koexistenzverordnung, KoexV (Vernehmlassungsentwurf vom 15. Januar 2013), pp. 7 ff.

[266] For example Report Canada, p. 345; Report Belgium, p. 142; Report Germany, pp. 99 f.

[267] Roland Norer, p. 194 (n. 208).

[268] Report Germany, p. 99. See Michael Greiner, Befassungskompetenz kommunaler Gremien mit Fragen der Gentechnik („Gentechnikfreie Zone"), KommunalPraxis BY (2004), p. 376; Hans-Dieter Laser, Ausbringen von genetisch veränderten Organismen und Pflanzen auf gemeindeeigenen Grundstücken, KommunalPraxis BY (2005), p. 384.

If farmers commit themselves to GMO-free agriculture, these commitments could result in GMO-free zones. Since the nature of such contracts is private, the zones would not be attributable to the EU Member State concerned.[269]

Particularly interesting is the among scholars much discussed question whether a **legally binding GMO-free zone** could be created lawfully under the umbrella of the current international, supranational and national legal regimes.[270]

As to the **WTO law**, the SPS Agreement might have an answer to this question. Since the Agreement's sanitary and phytosanitary measures encompass among others measures to protect human, animal or plant life from risks arising from diseases-causing organisms (Annex A, Art. 1 lit. a and b), it remains unclear if GMOs might be qualified as "disease-causing organism". In any case, some scholars advocate the application of the SPS Agreement on regulation on genetic engineering.[271] If this question of principle is answered in the affirmative, then Art. 6(2) may serve as starting point for GMO-free zones since it explicitly mentions the concept of pest- or disease-free areas.[272] The determination of such areas is to be based on factors such as geography, ecosystems, epidemiological surveillance and the effectiveness of sanitary or phytosanitary controls. The members have to provide the information necessary for an objective risk assessment. Thus, the SPS Agreement might contain a starting point for the creation of GMO-free zones in accordance with the WTO regime.

The case is different with the **EU law**: It is difficult to detect an applicable legal basis. The question raised in the German Report[273] of whether zones being completely free of any GMOs could be lawfully established directly on the basis of the *TFEU* has to be answered in the negative as a rule. Art. 114(5) TFEU provides for a derogation clause according to which EU-Member States may unilaterally introduce national provisions deviating from harmonisation measures adopted by the EU legislator. Such domestic derogations from Regulation (EC) No. 1829/2003 and Directive 2001/18/EC can hardly form the legal basis for a comprehensive ban of GMO cultivation in a Member State's territory or parts of it, though. The Member States bear the full burden of proof that such prohibitions covering all kinds of GM crops are "based on new scientific evidence relating to the protection of the environment … on grounds of a problem specific to that Member State". Accordingly, Member States would have to produce scientific evidence that GM plants are as

[269] Report Germany, p. 99.

[270] Cf. Erika Wagner/Richard Volgger, Die Errichtung von GVO-freien Zonen in der Europäischen Union (2013); Astrid Epiney/Bernhard Waldmann/Magnus Oeschger/Jennifer Heuck, Die Ausscheidung von gentechnikfreien Gebieten in der Schweiz de lege lata et de lege ferenda (2011); Hans-Georg Dederer, Weiterentwicklung des Gentechnikrechts – GVO-freie Zonen und sozioökonomische Kriterien der GVO-Zulassung (2010); Roland Norer, pp. 187 ff. (n. 208).

[271] Barbara Eggers, Die Entscheidung des WTO Appellate Body im Hormonfall, EuZW 1998, 148; Sabine Blacke, Risikoentscheidungen im europäischen Lebensmittelrecht (1998), pp. 862 f; Ferdinand Kerschner/Erika Wagner, Koexistenz zwischen Gentechnik, Landwirtschaft und Natur – rechtliche Rahmenbedingungen (2003), p. 100.

[272] Roland Norer, p. 189 (n. 208).

[273] Report Germany, pp. 99 f.

such inherently dangerous to human health and the environment because genetic engineering or genetic modification techniques respectively pose per se health and environmental risks. In fact, Upper Austria failed to base its (draft) law prohibiting the cultivation of GMOs entirely on the TFEU's derogation clause.[274]

GMO-free zones on the basis of other fields of law however seem legally feasible. As far as it concerns coexistence of genetically modified, conventional and organic crop production, the European Commission has adopted the *coexistence recommendation*[275] on the basis of Art. 26a(2) Directive 2001/18/EC. This not legally binding recommendation states that "under certain economic and natural conditions, Member States should consider the possibility to exclude GMO cultivation from large areas of their territory to avoid the unintended presence of GMOs in conventional and organic crops".[276] The establishment of a GMO-free zone as a measure of coexistence may, however, apply to specific GMOs only but not to all GMOs in general.[277] When examining the measures some national states have adopted for the sake of coexistence, especially the isolation distances (see section "Coexistence". below), the result may come close to the creation of GMO-free zones. Depending on the shape, size and dispersal of fields in a given region, GM farmers may not be able to abide by these isolation distances. Thus, in such a case, the respective region becomes de facto a GMO-free zone with regard to those GM crops to which the unrealisable isolation distances apply.[278]

Furthermore, the above (section "Safeguard clauses") mentioned *safeguarding clause* of Directive 2001/18/EC on the deliberate emission of GMOs into the environment (Art. 23) admits the possibility for States to ban GM crops in their own territory for reasons pertaining to the safeguarding of health. The national implementation of this clause may also lead to de facto GMO-free zones. Additionally, Art. 26a introduced into the body of Directive 2001/18/EC lays down that "the Member States can adopt all the appropriate measures in order to avoid the involuntary presence of GMOs in other products", and this does not jeopardise the possibility for Member States to resort to the emergency measures cited in Art. 34 Regulation (EC) No. 1829/2003.

Finally, **natural conservation measures** may also result in GMO-free zones.[279]

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[274] Joined Cases T-366/03 and T-235/04, Land Oberösterreich, ECR 2005, p. II-4005, para 36 ff. This judgment was upheld by the ECJ, Joined Cases C-439/05 P and C-454/05 P Land Oberösterreich [2007] ECR I-7141, par. 60 ff.

[275] Commission Recommendation No. 2010/C 200/01 of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops (OJ C 200, 22.7.2010, p. 1).

[276] Para. 2.4 Commission Recommendation No. 2010/C 200/01 (n. 275).

[277] Report Germany, p. 97. For the purpose of coexistence measures is to avoid the unintended presence of GMOs in conventional or organic crops.

[278] Report Germany, p. 98.

[279] For an in-depth analysis see Hans-Georg Dederer, pp. 12 ff. (n. 270).

Opt-out

Henceforth, the aforementioned (see section "EU law") Proposal for a Regulation amending Directive 2001/18/EC[280] might serve as new legal basis for GMO-free zones. The Commission, following a request by a number of States, created an opt-out clause for Member States in relation to GM cultivation (proposed Art. 26b) by which "the Member States can adopt measures that limit or forbid the cultivation of all or of certain specified GMOs throughout their territory or in part of it". The report[281] annexed to the above-described proposal also states very clearly that the new article "is exclusively concerned with the freedom of Member States to forbid/limit the cultivation of the GM varieties" on their own territories "on the national/regional/local level". It is also made clear that the impact assessments to justify the prohibition or limitation of GM cultivations can be adopted in those Member States whose constitutional organisation provides for such measures, by the regional or local territorial bodies.[282]

It is quite likely that many states would avail of such an opt-out provision, but for the time being it remains uncertain as to whether they will have the option as the proposal has yet to be approved by the EU legislative bodies.

Coexistence

Ensuring farmers' and consumers' freedom of choice depends on one important factor: the question of coexistence.[283] Coexistence means the simultaneous cultivation of different crops side by side; with regard to genetic engineering the coexistence of conventional, organic and GM crops. Thereby, in principle farmers can choose which crops they want to cultivate. According to the Commission's guidelines on the coexistence of genetically modified crops with conventional and organic agriculture dating from 2003 to 2010,[284] none of the mentioned production systems shall be banned in the EU. As a consequence, not only the farmers but also the consumers will be enabled to choose between genetically modified food and food that is free of GMOs.

[280] N. 130.

[281] N. 135.

[282] Report Italy, p. 231.

[283] See e.g. Ferdinand Kerschner/Erika Wagner, Koexistenz zwischen Gentechnik, Landwirtschaft und Natur – rechtliche Rahmenbedingungen (2003); Rainer J. Schweizer/Christoph Errass/Stefan Kohler (eds.), Koexistenz der Produktion mit und ohne gentechnisch veränderte Organsimen in der Landwirtschaft (2012).

[284] Commission Recommendation 2003/556/EG of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (OJ L 189, 29.7.2003, p. 36), repealed by Commission Recommendation No. 2010/C 200/01 of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops (OJ C 200, 22.7.2010, p. 1).

Art. 26a Directive 2001/18/EC (inserted by Regulation 1829/2003) allows for Member States to "take appropriate measures to avoid the unintended presence of GMOs in other products", i.e. to facilitate the coexistence of GM crops alongside non-GM crops. Although within the competence of the Member States, the Commission nonetheless has a role laid out for it in Art. 26a(2) of the Directive and as such has provided guidance documents in relation to coexistence, as well as taking a number of other steps that could be seen – according to the Irish Report[285] – to reduce the freedom or discretion of the Member States.[286] As far as it concerns coexistence of GM, conventional and organic crop production, the European **Commission** has adopted the **recommendation**[287] in 2010. This recommendation is a soft law document and not legally binding,[288] although it is likely to be of highly influential value to the Member States and in any case before the Court of Justice of the EU.[289] The Recommendation outlines ways of dealing with GMOs in view of the economic impact and the viability of the alternative crop. GMO-free cultivation is somewhat treated preferentially, meaning that coexistence measures are favoured by the Commission in order to protect farmers using conventional seed and plants.[290] All in all, the Recommendation seems to be more aware of the interests of organic farmers if compared to the Recommendation issued in 2003. Accordingly, the Recommendation also stresses labelling thresholds and addresses questions as to what extent products are still meeting production requirements for organic farmers if there is an admixture of GMOs. Thus, the Commission does not set the goal of zero tolerance, but rather to mollify the economic impact of unavoidable admixtures.[291] National measures would, according to the Recommendation, include buffer zones or special procedures for cleaning equipment.

In the *Member States*, various approaches on the regulation of coexistence can be found in view of the implementation of Art. 26a Directive 2001/18/EC.

In *Belgium* for instance, both the Flemish and Walloon Region have a general legal framework on coexistence of genetic modified cultures with conventional and organic cultures.[292] While the decree of the Walloon Region establishes GMO-free

[285] Report Ireland, p. 189.

[286] E.g. the creation of a Coexistence Network – Commission Decision No. 2005/463/EC of 21 June 2005 establishing a network group for the exchange and coordination of information concerning coexistence of genetically modified, conventional and organic crops (OJ L 164, 24.6.2005, p. 50) – and a Coexistence Bureau – Maria Lee, Multi-Level Governance of GMOs in the EU: ambiguity and hierarchy, in: Luc Bodiguel/Michael Cardwell (eds.), The Regulation of GMOs: Comparative Approaches (2010), pp. 101 ff.

[287] N. 275. See Mary Dobbs, Excluding Coexistence of GMOs? The impact of the EU Commission's 2010 Recommendation on Coexistence, RECIEL 2011, p. 180.

[288] See Art. 288(5) TFEU.

[289] Report Ireland, p. 189.

[290] Report Ireland, p. 189.

[291] Generally coexistence measures will favour one agri-type over another; Les Levidow/Karin Boschert, Coexistence or contradiction? GM crops versus alternative agricultures in Europe?, 39 GEOFORUM 174, 174, 181, 187 (2008).

[292] Report Belgium, pp. 141 ff.

zones (see section "Inventory" above), the Decree of 3 April 2009 of the Flemish Region, which is applicable to all cultures of GMOs in that region that would be authorised in the framework of Directive 2001/18/EC, aims to ensure the free choice of farmers between genetically modified, conventional and organic cultures and to avoid economic losses for conventional and organic cultures due to unintended presence of GMOs above the EU threshold value for labelling. It obliges farmers (and their contractors) who intend to cultivate GMOs to follow a specific training. They have to notify the Flemish authorities and neighbouring farmers in advance of that intention. These neighbouring farmers can object to the intended culture on the basis of a reasoned proper economic interest. The farmers who cultivate GMOs have to contribute to a Public Fund for compensation of economic losses. A Coexistence Commission has to assess the objections from neighbouring farmers and the applications for compensation. All cultures of GMOs are registered in a public register. On the basis of this Decree, the Flemish Government has adopted some general and specific rules.

In *Ireland*, a report on the matter of coexistence was published in 2005.[293] The resulting recommendations were to entail mandatory and voluntary guidelines that were primarily of an ex ante nature, but also did consider the issue of economic liability. Some of the key recommendations related to prior approval from the Department and to buffer zones. However, currently they remain as non-binding recommendations, which have been left sit without any statutory implementation. Considering the lack of cultivation in Ireland, it is not surprising that not much effort is apparent in reviving these recommendations.

In *Finland* the government is preparing a bill in accordance with the recommendation of the EU commission.[294] The proposal would allow GMO cultivation and it sets certain conditions like distance requirements and more.

In *Switzerland* according to Art. 7 GTA, GMOs may be handled only in such a way that they, their metabolic products or wastes do not impair production that does not involve GMOs, or limit consumers' freedom of choice.[295] This article intends not only to ensure a neighbourly field to field coexistence, but also to guarantee that in each production phase and after each production process, products can be offered on the market which have been produced without GMOs. According to the Swiss Report, the departure point must be a principle of "zero" pollution. Otherwise an unacceptable tolerance of contamination would be assumed. To reach this goal, measures must be taken so that threshold values are not exceeded and to prevent that such contamination occurs. If a contamination occurs despite the measures taken, the main issue to discuss is the question where to draw the line. This should at least be regulated by decree of the Federal Council.[296]

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[293] Available at: http://www.agriculture.gov.ie/media/migration/publications/2005/coexistenceofgmandnon-gmcropsinireland/report.pdf. Report Ireland, p. 189.

[294] Report Finland, pp. 156 f.

[295] Report Switzerland, p. 278.

[296] See Rainer J. Schweizer/Isabelle Wildhaber/David Rechsteiner, Vorschläge für eine Schweizer Koexistenzordnung, in: Rainer J. Schweizer/Christoph Errass/Stefan Kohler, pp. 209 ff. (n. 206).

Outside the EU only very few states have legislated on coexistence. The main producer states of GMOs like the USA or Canada as well as Argentina or Brazil did not anchor any rules on coexistence in their respective legislations.

Admission of GMOs

In practice, every state participating in this comparative report has legislated on the admission of GMOs in food production.[297] Foodstuffs with GMOs require an authorisation for being put into circulation. In most cases, the regulation follows a step-by-step-principle. Rules of procedure, often very detailed ones, provide a backbone for the coordination between different authorities, the involvement of advisory committees[298] or the documentation requirements.

Within the EU for the Member States the admission is primarily governed by EU law which is complemented by national law as far as it concerns procedural aspects. The authorisation process commences at a national level, but the risk assessment and decision are made at the EU level. EU law provides that GM food and feed may be placed on the market on the basis of an *authorisation* only.

This *requirement* of a marketing authorisation is laid down in Art. 4(2) Regulation (EC) No. 1829/2003. Thus, GM food law does not follow the regulatory approach of general food law according to which food may be placed on the market without prior approval by a governmental authority.[299] In some cases, GM food may probably need an additional authorisation granted on the basis of Regulation (EC) No. 258/97[300] "where they fall under one or more of the categories referred to in Art. 1(2)(a) of Regulation (EC) No. 258/97 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation".[301] Any food or feed receiving authorisation at the EU level is automatically authorised within all the Member States.

It should be noted that, on the one hand, not all kinds of genetic modification give rise to a "GMO" because some breeding techniques are not considered to result in

[297] Macau SAR however is an exception since there is no explicit mention of GMOs in the legal regime governing food safety. Therefore it must be generally concluded that GMOs are admitted, both in terms of local production and the import of foreign products containing GMOs; Report Macau SAR, pp. 434 f.

[298] E.g. in Switzerland the Federal Biosafety Committee (FBSC) and the Federal Ethics Committee on Non-Human Biotechnology (ECNH); Report Switzerland, p. 275. In the EU (on a voluntary basis) the European Group on Ethics in Science and New Technologies; Report Germany, pp. 107 f.

[299] I.e. the person placing food on the market is fully and solely responsible that the food safety requirements are fulfilled and consumers are not misled. See Art. 14 Regulation (EC) No. 178/2002 and Report Germany, pp. 100 f. with further references.

[300] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

[301] Recital 11 Regulation (EU) No. 1829/2003 (n. 143).

"genetic modification" within the meaning of EU genetic engineering law.[302] On the other hand, the authorisation requirement of Regulation (EC) No. 1829/2003 covers GMOs as such for food use, food containing or consisting of GMOs, and food produced from GMOs or containing ingredients produced from GMOs.[303] As a consequence, food produced "with" GMOs is beyond the regulation's scope of application regarding the authorisation requirement.[304] In cases of doubt the European Commission may initiate a so-called "comitology procedure" for the purpose of clarifying whether a certain type of food is subject to the authorisation requirement.[305]

The applicant applies for this GM food authorisation under the rules of *procedure* set out in Regulation (EC) No. 1829/2003[306] and governed by an interplay of national and supranational authorities. The application has to be submitted to the competent authority of an EU Member State, which has to inform the European Food Safety Authority (EFSA) without delay, and pass the application and any further information supplied by the applicant to EFSA. EFSA, in turn, has to inform the other EU-Member States and the European Commission without delay and to circulate the application and any additional information supplied by the applicant among them. In addition, EFSA must make the applicant's summary of his or her dossier available to the public. When EFSA made its opinion – destined as a scientific advice to the Commission – it has to refer the case to the European Commission, to the Member States and to the applicant. In addition, EFSA must make its opinion public.[307] Hence, a notice-and-comment-procedure starts: The public may make comments to the European Commission within a period of 30 days. It is up to the Commission to draw up a draft decision, which is processed within the framework of the so called "comitology procedure".[308] This procedure is highly politicised because it involves the Standing Committee of the Food Chain and Animal Health, which is made up of representatives from the Member States who are or can be, bound by instructions of their respective governments, and the Council which is composed of ministers. In past, decisions were delivered because no qualified majority was reached at the Regulatory Committee and at the Council level. After a decision has been taken, the Commission must publish details of the decision in the Official Journal of the EU. Despite the fact that time limits are set for most of the

[302] See Annex I A, Part 2 Directive 2001/18/EC (n. 130); Report Italy.

[303] Art. 3(1)(a-c) Regulation (EC) No. 1829/2003 (n. 143).

[304] GM processing aids or food produced with the help of GM processing aids are not covered by Regulation (EC) No. 1829/2003 (n. 143). Also, milk from cows fed with GM plants is not subject to the regulation's authorisation requirement. If, on the other hand, material from GMOs is present in the food, such food is considered GM food and, hence, covered by the market authorisation requirement under Regulation (EC) No. 1829/2003 even if the presence of the GMO or any GM material is undetectable. See Report Germany, p. 101 f.

[305] Art. 3(2) Regulation (EC) No. 1829/2003 (n. 143).

[306] See Recital 33, Art. 5–7 Regulation (EC) No. 1829/2003 (n. 143).

[307] Any information which the applicant has classed as confidential will be deleted, see Art. 6(7)(1) in connection with Art. 30 Regulation (EC) No. 1829/2003 (n. 143).

[308] In detail Report Germany, pp. 108 f.; Report Ireland, pp. 183 ff.

steps of the authorisation procedure, the duration of the whole process is more or less unpredictable. As regulations are directly applicable in the Member States, national particularities are only possible within narrow limits.[309]

Outside the EU, *Switzerland* requires foodstuffs containing GMOs to meet material as well as procedural requirements (Art. 6–9 and 12 GTA) in order to be put into circulation.[310] Foodstuffs with GMOs may only be handled in such a way that they cannot endanger human beings, animals or the environment and do not harm biological diversity or the sustainable use thereof (Art. 6(1)(a and b) GTA). In this respect, environmental requirements are to be met in addition to health requirements. These requirements are specified in three substantive ordinances, where the authorised GMOs are listed at the end.[311]

In *Norway*, EU approved products containing processed genetic material are not automatically approved nationally.[312] A separate application must be submitted to the Norwegian Food Safety Authority regarding processed GM food and feed products. For living GM food and feed products, a separate application to Norway is not necessary. In accordance with the EEA Agreement, Norway must evaluate all GMO applications received by any EU-Member State, and the final decision is with the Norwegian Ministry of the Environment.

In *Canada*, the admission of GMOs is regulated at the federal level in the Food and Drugs Regulations through a pre-market notification requirement.[313] Market approval will be necessary if the foodstuff carries some trait not previously found within the species, regardless of whether they be created through genetic engineering or more traditional breeding methods. With the pre-market notification and a scientific assessment, the market authorisation follows a two-steps process. Finally, Health Canada will post a summary of the decision on its website (the Novel Foods and Ingredients page).[314]

In *Mexico* as well, GMOs destined for the processing of foods for human consumption are subject to authorisation.[315] Once the Secretariat of Health receives an authorisation application, and provided that it complies with all the information and

[309] The implementation in Ireland for instance attributes a somewhat greater role to the initial competent authority in comparison with the authorisation procedure in Regulation (EC) No. 1829/2003 (n. 143); Report Ireland, p. 185. The rules of the German GenTG governing the placing on the market of products containing or consisting of GMOs (Sec. 14 ff. GenTG) are inapplicable; Report Germany, p. 101.

[310] Report Switzerland, pp. 279 f.

[311] Annex 2 Ordinance of the FDHA about genetically modified foodstuffs (OGMF) of 23 November 2005 (SR 817.022.51). See the summary of the appraisals: http://www.bag.admin.ch/themen/lebensmittel/04858/04863/10021/index.html?lang=de

[312] Report Norway, p. 255.

[313] Division 28 of Part B of the Food and Drugs Regulations; Report Canada, p. 345.

[314] See e.g. CFIA, "DD2005-53: Determination of the Safety of Monsanto Canada Inc.'s Roundup Ready® Alfalfa (Medicago sativa L.) Events J101 and J163", http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd2005-53/eng/1311630531051/1311631992012

[315] Report Mexico, p. 375.

requirements established in the Law on Biosafety of Genetically Modified Organisms (LBOGM), it will remit it to the Registry to be inscribed and published. The Secretariat of Health will issue its resolution once it has analysed the information and documentation provided by the interested person.

Threshold Values

Threshold values define within which limits traces of genetic modifications are legally irrelevant.

Within the EU, such threshold values either occur in the form of an exemption from being subjected to an authorisation (authorisation thresholds) or as derogation from labelling obligations (labelling thresholds).[316] There are special standards to be taken note of for organic farming and for seed. But there is no threshold for products regarding the maximum level of GMOs in them (or regarding the use of GMOs in producing them).

The **authorisation thresholds** of 0.1 %-threshold applies to feed only. Art. 2 Regulation (EU) No. 619/2011[317] states that feed with traces of GM material below the threshold of 0.1 % since 2011 does not make a market authorisation according to Art. 16(2) Regulation (EC) No. 1829/2003 necessary, if the GM material meets certain requirements. Nevertheless, Member States have to record the test results and must notify the European Commission as well as the other Member States on an annual basis.[318] The Commission or any Member State may, if need be, adopt emergency measures in accordance with Regulation (EC) No. 178/2002.[319] If the 0.1 %-threshold is exceeded or if the detected GM material does not conform to the specific requirements laid down in Regulation (EC) No. 619/2011, the respective feed has to be considered non-compliant with Regulation (EC) No. 1829/2003.[320] Under these circumstances, the feed must not be placed on the market since it cannot be authorised under Regulation (EC) No. 1829/2003.[321] The authorisation threshold thus runs counter to the principle of zero tolerance, according to which bringing GMOs into market is always subject to an authorisation.

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[316] Isabelle Wildhaber, Ungewollte Auskreuzungen und die Schwellenwerts-Debatte im Gentechnikrecht, AJP/PJA (2009), pp. 852 ff.; Report Germany, pp. 110 ff.

[317] Commission Regulation (EU) No. 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired (OJ L 166, 25.6.2011, p. 9).

[318] Art. 6(2)(1) Regulation (EU) No. 619/2011 (n. 317).

[319] Recital 18 and Art. 6(3) Regulation (EU) No. 619/2011 (n. 317) in connection with Art. 53, 54 Regulation (EC) No. 178/2002 (n. 137).

[320] Art. 6(1)(1), Annex II B 2 Regulation (EU) No. 619/2011 (n. 317).

[321] Art. 16(2) Regulation (EC) No. 1829/2003 (n. 143).

Up to 18 April 2007, the well-known 0.5 %-threshold laid down in Regulation (EC) No. 1829/2003 was in force.[322] According to a transitional provision, 'conventional' food was not subject to the market authorisation requirement either under Regulation (EC) No. 1829/2003[323] or under Directive 2001/18/EC[324] if material which contained, consisted of or was produced from GMOs in a proportion no higher than 0.5 % was present in the food and if these GM traces conformed to certain requirements.[325]

As to the **labelling threshold**, according to Art. 12(2) Regulation (EC) No. 1829/2003 a limit of 0.9 % applies to GM specific labelling of GM food. GM specific labelling is not required if food contains "material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 % of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable". The same threshold applies to "products intended for direct use as food or … for processing".[326] If the labelling threshold of 0.9 % is exceeded, the respective food is subject to the GM specific labelling requirements (see section "Labelling" below).

Further thresholds in EU law are to be found for **organic farming**. Under the regime of the former Regulation (EEC) No. 2092/91[327] on organic production, GMOs or any product derived from GMOs were not allowed according to Art. 6(2) (d). Additionally, seed had to be produced in accordance with the rules on organic production for at least two growing seasons. Art. 13 however contained a legal basis for defining thresholds. Thus, the ban on the use of GMOs was not abrogated, yet the Commission considered that due to the absence of a specific provision, the common thresholds for food and feed should be applied.[328] Presently, the Regulation (EC) No. 834/2007 on organic production and labelling[329] reaffirms the common principle that organic production must abstain from using GMOs or products produced from or by GMOs with the exception of veterinary medicinal products.[330] Exception from the production rules for organic farming may be made where it is necessary, i.e. when food and feed additives and other substances are not available

[322] See Art. 47(5) in connection with Art. 49 (5) Regulation (EC) No. 1829/2003; Art. 12a(2) Directive 2001/18/EC.

[323] Art. 4(2) Regulation (EC) No. 1829/2003.

[324] Art. 13(1)(1) Directive 2001/18/EC.

[325] See Art. 47(1) Regulation (EC) No. 1829/2003 (n. 143); Art. 12a(1) Directive 2001/18/EC. As to the history of the norm, see Report Ireland, pp. 182 ff.; Isabelle Wildhaber (n. 316), p. 852.

[326] Art. 4(8) Regulation (EU) No. 1830/2003 (n. 131).

[327] Council Regulation (EEC) No. 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ L 198, 24.6.1991, p. 1).

[328] Commission Recommendation on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming, 2.2.3 (n. 284). For criticism expressed in literature, see Isabelle Wildhaber (n. 316), p. 855.

[329] Regulation (EC) No. 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No. 2092/1991 (n. 327).

[330] Art. 4(a)(iii), Art. 9(1) Regulation (EC) No. 834/2007 (n. 140).

on the market other than produced by GMOs. The additives and substances may then be produced conventionally, provided that the Commission has granted an exception from the production rules laid down in the Regulation.[331] As to the rules on labelling, the threshold value of 0.9 % is applicable if the farmer can prove that the traces of GMOs were adventitious and technically unavoidable.[332] In such cases, terms like "bio" or "eco" may still be used in the labelling of such organic products.

Concerning **seed** containing adventitious or technically unavoidable traces of GMOs, the question of labelling remains unclear; a correspondent legal basis in EU law is lacking so far. The threshold of 0.9 % set forth by Regulation (EC) No. 1829/2003 mentioned above is only applicable for bringing food or feed into market and does not contain rules on labelling of seed intended to be introduced to the market. Art. 12a Directive 2001/18/EC, introduced by Regulation (EC) No. 1829/2003, does not allow to deduce a threshold value for contamination of seed either. The same can be said about Art. 21(3) Directive 2001/18/EC, which states that products intended for direct processing are subject to a threshold of 0.9 %. The ceiling whose transgression triggers the obligation of declaration has yet to be defined, i.e. in the form of a labelling threshold for contaminations of seed.[333] Indeed, this weakens the legal security in some countries since the leeway leads to contradictory decisions by the different authorities. Thus, over many years, a bitter discussion about introducing a threshold for GMOs in seed has been led most controversially. The solutions proposed by the Commission envisages thresholds between 0.3 and 0.5 % depending on the type of crop. However, all attempts to come to a political solution on a European level have failed.[334]

Outside the EU, threshold values are widely unknown,[335] except where they are deduced from EU law for countries interacting economically and legally with the EU.

Thus, in *Norway* the current threshold of processed genetic material is 0.9 % in imported food and feed if the product has been approved by the EU, provided that there is an accidental or technically unavoidable presence of processed genetic material, and provided that the enterprise can document such causes for the presence.[336] Moreover, the Norwegian regulations allow for a presence of 0.5 % GMOs in imported products in the absence of a EU approval, but only if the GM material has been subject to a risk assessment and found to be safe.

In *Switzerland* Art. 7(7) OGMF[337] defines the threshold and under what conditions labelling can be waived.[338] The reference may be waived when no ingredient

[331] Art. 22(1) and (2)(g) Regulation (EC) No. 834/2007 (n. 140).

[332] Recital 10 and 30, Art. 23 Regulation (EC) No. 834/2007 (n. 140).

[333] Daniela Nowotny, p. 406 (n. 25); Isabelle Wildhaber (n. 316), pp. 855 f.

[334] In detail Isabelle Wildhaber (n. 316), pp. 855 f.

[335] Report Mexico, pp. 376 f.; Report Macau SAR, p. 435; Report Taiwan, p. 413, with the exception of a 5 %-threshold for triggering the mandatory labelling requirement.

[336] Report Norway, pp. 255 f.

[337] N. 311.

[338] Report Switzerland, p. 286.

of material that consists of, contains or is produced from GMOs exceeds the amount of 0.9 % by mass and when there is proof that appropriate measures have been taken to avoid the presence of such material in the ingredient.[339]

In the *USA* "the US Organic Food Production Act[340] established a certification program for organic production."[341] According to the National Organic Program standards, "crops labeled as organic may not use GM technology or GM inputs."[342] "Livestock products sold or labeled as organic must come from animals raised under organic management with organically produced feed."[343] But US law – as opposed to the 0.9 %-threshold in the EU – "does not impose a maximum threshold of GM material for foods to be certified and labeled as organic. Therefore, organic certification does not guarantee the absence of GM material, but only that GM inputs were not intentionally used in production."[344]

Implementation, Enforcement, Controlling Regime

Within the EU, under Regulation (EC) No. 1829/2003, the applicant may choose in which Member State he would like to file the application for market authorisation of GM food.[345] The national reports specify which authorities are competent in their states. Usually, those are also the national competent authorities which may ask the applicant, through EFSA, to provide additional data or information,[346] which may be asked to carry out the food safety assessment[347] or the environmental risk assessment[348] and which may be consulted by EFSA with regard to environmental safety standards.[349] These authorities are typically Ministries of Health or their agencies.[350]

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[339] Art. 7(7bis) OGMF (n. 311).

[340] 7 U.S.C. §§ 6501–6523; 7 C.F.R. part 205.

[341] Report USA, p. 294.

[342] Report USA, p. 294, citing 7 C.F.R. § 205.105. "The unintentional presence of a detectable GM residue may not affect organic status, if the operator did not use genetic modification and took reasonable steps to avoid contacts with GMOs."

[343] Report USA, p. 294, quoting 7 U.S.C. § 6508; 7 C.F.R. §§ 205.236, 205.237.

[344] Report USA, p. 294.

[345] Cf. Art. 5(2)(1) Regulation (EC) No. 1829/2003 (n. 143).

[346] Art. 6(2) Regulation (EC) No. 1829/2003 (n. 143).

[347] Art. 6(3)(b) Regulation (EC) No. 1829/2003 (n. 143).

[348] Art. 6(3)(c) Regulation (EC) No. 1829/2003 (n. 143).

[349] Art. 6(4)(3) Regulation (EC) No. 1829/2003 (n. 143).

[350] For example German Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL), Report Germany, p. 111; Norwegian Food Safety Authority, Report Norway, p. 255; Belgian Directorate General for the Protection of Public Health, Report Belgium, p. 146; Food Safety Center in Macau SAR, in planning, Report Macau SAR, p. 432.

The holder of a market authorisation is subject to certain reporting requirements. In particular, authorisation-holders have to submit monitoring reports to the Commission.[351] These monitoring reports have to be made available to the public after any information acknowledged to be confidential has been deleted.[352]

The competence of controlling the compliance with Regulations (EC) No. 1829/2003, 1830/2003 and 1946/2003 is with regional or federal authorities.[353] The applicable sanctions are essentially in accordance with those used in the general administrative law. There are in particular administrative fines; temporal or definitive closure; confiscation of instruments, exemplars, obtained organisms or products; withdrawal/suspension or revocation of licenses and authorisations; prohibition of the experimental or commercial release of GMOs, to name but a few.[354]

In general, it is frequently being criticised that the EU's system for the authorisation of GM agri-food products for import an Cultivation is still not being applied correctly. Whereas the underlying legislative framework is assessed as workable, GM policy and regulation has become a political football.[355]

Outside the EU, some reports give an account of similar regulations and sanctions.[356]

Labelling

Closely connected to the admission of GM products, questions concerning the labelling of these products arise. Not only in context with thresholds, but also in order to allow the consumer a freedom of choice and to acquire information concerning GMO foodstuffs, labelling is paramount. The Italian Report refers in this context to the biotechnology food chain,[357] especially its last segment, the introduction of GM food onto the market.

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[351] Art. 9(1)(2) Regulation (EC) No. 1829/2003 (n. 143).

[352] Art. 9(1)(3) Regulation (EC) No. 1829/2003 (n. 143).

[353] For example the German "Länder", Report Germany, p. 114; Belgian Federal Agency for the Safety of the Food Chain, Report Belgium, p. 146.

[354] Report Belgium, p. 146.

[355] See Darren Abrahams, Legal Considerations related to the Authorisation, Import and Cultivation of GM Crops in the European Union: A Precedent for other regulated Industries?, 13 BSLR 5, pp. 155 ff.

[356] Report Mexico, pp. 380 f.

[357] This chain can be decomposed into the following phases: the phase of utilisation purely for research and for study of the biotechnological material; the potential phase of patenting the procedure and the biotechnological product; the subsequent phase in which debate has decided in favour of deliberate emission of the genetically modified organism into the environment for the purpose of growing crops; and finally the phase of introducing onto the market the genetically modified foodstuffs that it has been possible to grow and produce. All these stages require specific authorisations; Report Italy, p. 235.

Labelling Regime

Within the EU, the use of labels declaring food free of GMOs is, in principle, not prohibited by EU law. It is, in any case, not regulated explicitly in EU law or on a national level. The EU Commission is taking the introduction of a EU-wide voluntary framework governing the use of the label GM-free into consideration.[358] For the time being, any national law on labelling products as free of GMOs must comply with EU law.

By contrast, labelling in accordance with Directive 2001/18/EC, Regulation (EC) No. 1829/2003 or No. 1830/2003 means the exact opposite, i.e. the declaration as food containing GMOs. GM specific labelling is in principle obligatory for GM food covered by Regulation (EC) No. 1829/2003, thus GM food must be labelled using terms such as "genetically modified", "produced from genetically modified (name of organism/ingredient)", "contains genetically modified (name of organisms)" or "contains (name of ingredient) produced from genetically modified (organisms)".[359] These labelling requirements do not apply to foods (and products for food produced from GMOs) containing GM material in a proportion no higher than 0.9 % of the food ingredients considered individually or food consisting of a single ingredient; always on the condition that the presence of GM traces is adventitious or technically unavoidable.[360]

In *Belgium* no specific national rules in this respect have been adopted.[361] However general labelling requirements are laid down in different Articles of the Royal Decree of 21 February 2005, and those provisions are subject to the sanction provisions of the Act of 20 July 1991 and the various sectorial Acts governing specific categories of goods, products or materials.

The case is different with *Germany*, where food free of GMOs may be labelled "ohne Gentechnik" ("without genetic engineering") only, while other labels, e.g., "gentechnikfrei" ("genetic engineering free") are prohibited.[362] German law comprises detailed rules in reference to the labelling requirements of Regulation (EC) No. 1829/2003 and No. 1830/2003.[363] The rules are, however, visibly less strict. The prohibition to feed animals on GM feed for instance is restricted to a certain period of time before the start of the food production process[364] or the use of feed additives produced with, or by, GMOs, e.g. vitamins, does not preclude the use of the "ohne Gentechnik"-label.[365]

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[358] Report Ireland, p. 197.

[359] Cf. Art. 13(1)(a-c) Regulation (EC) No. 1829/2003 (n. 143). In detail Report Germany, p. 116.

[360] Art. 12(2) Regulation (EC) No. 1829/2003 (n. 143); Art. 4(8), 5(3) Regulation (EC) No. 1830/2003 (n. 131).

[361] Report Belgium, p. 147; also Report Finland, pp. 167 f.

[362] Sec. 3a(1)(2) EGGenTDurchfG (n. 170). The label "ohne Gentechnik" signifies that the food was produced without the use of genetic engineering techniques; Report Germany, pp. 114 f.

[363] Report Germany, p. 115.

[364] Sec. 3a(4)(2) EGGenTDurchfG (n. 170).

[365] http://www.transgen.de/recht/kennzeichnung/280.doku.html, Report Germany, p. 115.

Outside the EU, in *Switzerland* for instance, according to Art. 17(1) GTA, any person putting GMOs into circulation must label them as such for the benefit of the recipient, in order to ensure freedom of choice for the consumer under Art. 7 and to prevent product fraud.[366] The labelling must contain the words "genetically modified". Mixtures, articles and products containing GMOs are also regarded as genetically modified. As such, they must also be labelled.[367] Since the contamination with GMOs cannot be completely excluded, the legislator has granted the Federal Council the competence to lay down threshold values below which labelling is not required for mixtures, articles and products that unintentionally[368] contain traces of GMOs.[369] These requirements have been implemented in Art. 7 OGMF in more detail. Thus, the wording in which the labelling must be effected, defines "produced from genetically modified X" (for food and additives that are products of GMO) or "made with genetically modified X" (for microorganisms in food). The 0.9 %-threshold is defined and it is stated that labelling can be waived where there is proof that appropriate measures have been taken to avoid the presence of such material in the ingredient. The criteria for negative labelling are laid down as well. Since for organic products the use of GMO is not permitted under Art. 3(c) Organic Farming Ordinance,[370] organic food may not be negatively labelled. With regard to the threshold value, the same rules as to the regular products apply.[371]

Norway as well adopted law on labelling: The 2002 Norwegian Feed regulation and the 1992 Norwegian Labelling regulation both specify the labelling requirements for food and feed produced from GMOs, as well as for GM food and feed.[372] The labelling requirement does not apply if the content of the processed genetic material in a product is less than 0.9 %, provided that there is an accidental or technically unavoidable presence of authorised processed genetic material.[373]

Mexico's[374] and *Taiwan*'s[375] labelling regimes also explicitly refer to GMOs. In Taiwan a mandatory labelling scheme for GM or "GM included" produce applies to

[366] Report Switzerland, p. 285.

[367] Art. 5(1) and 17(1) GTA (n. 171).

[368] Traces of genetically modified organisms are considered to be unintentional if the person responsible for providing labelling proves that the product flows have been carefully monitored and recorded; Art. 17(3) GTA.

[369] Art. 17(2) GTA (n. 171).

[370] Ordinance on organic farming and the labelling of organic products and foods of 22 September 1997 (SR 910.18).

[371] See Judgement of the Federal Court 2A.357/2002 of 13 February 2003, considerations 3 and 4; Report Switzerland, p. 286.

[372] Sec. 4b 1st part Feed Regulation; Section 10c 1st part Labelling Regulation. Report Norway, p. 256.

[373] Sec. 10c 2nd part Foodstuff regulation; Section 4b 2nd part Feed regulation.

[374] Report Mexico, p. 379.

[375] Report Taiwan, p. 414.

products that contain GM soybean and corn. The requirement for labelling applies when the weight of the GM ingredients is equal to or greater than 5 % of the total weight of the food product.[376] The label must be affixed on a prominent place on the product and the font size and the width should not be less than 2 mm.[377] A voluntary labelling scheme of "non-GM" products from 2011 – in contrast to EU law – applies to those products using non-GM soybean or corn as a raw material.[378] Food products that are the result of the unintentional mixing of GM soybean or corn totalling less than 5 % during the cultivation or storage process would be considered as non-GM.[379] Special labelling provisions apply to GM plants.[380]

By contrast, the labelling schemes in Canada,[381] Macau SAR[382] and the federal level of the USA[383] do not mention GMOs.

In the *USA*, a 2000 court decision[384] upheld the Food & Drug Administration's (FDA) "decision not to require labels for GM food" "If no material difference exists between GM and non GM foods, the court indicated, it would be misbranding to label the GM product as different."[385] Public opinion is very divided on this issue.[386] Contrary to the absence of a federal regulation, a few state laws will require labelling of GM products.[387]

In *Canada* GMO labelling, in fact, remains voluntary which amounts to stating that there is none. GMOs are part of Canadian menus, to an extent unknown to consumers. The only exception is organic farming. Conversely, labelling affects GMO-free foodstuff (organic). Organic Products Regulations are enforced alongside the Canadian Organic Standards, which defines the practices to be followed in order for a product to be labelled organic.[388]

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[376] Art. 1 Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[377] Art. 5 Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[378] Art. 2 and 7 Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[379] Art. 3 Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[380] Ordinance of Packaging and labelling for GM Plants; Report Taiwan, p. 415.

[381] Report Canada, pp. 347 ff.

[382] Report Macau SAR, p. 437 ff.

[383] Report USA, p. 320: "GM food products need not be labelled as GM unless the food itself differs materially from similar foods".

[384] Report USA, p. 320.

[385] Report USA, p. 321: "Because the FDA had determined that genetic modification does not alter foods materially, a determination to which the court granted deference, the FDA lacked a legal basis for requiring labels, even in the face of consumer demand".

[386] Report USA, p. 322.

[387] See Report USA, pp. 323 ff., also to constitutional issues, natural labels and voluntary labelling.

[388] In detail Report Canada, pp. 348 ff.

Legislation Addressing Labelling Fraud

GM-free labelling which is not in conformity with the labelling regime or misleading labelling is punishable. So for example in Ireland, where there has been some mislabelling identified by both non-governmental organisations (NGOs) and the Food Safety Authority of Ireland (FSAI).[389]

Within the EU, violations of labelling rules under Regulation (EC) No. 1829/2003 and No. 1830/2003 constitute administrative offences.[390] Art. 11 Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from GMO requires Member States to lay down the rules on penalties applicable to infringements of this Regulation and to take all measures necessary to ensure their implementation.[391] Additionally, the labelling of GM foods has to comply with the general labelling requirements laid down in Directive 2000/13/EC.[392] Misleading labelling can be considered unfair competition as well.

The Member States chose various approaches in this context.[393] In *Germany* for instance, the relevant special legislative acts as well as generally – in the case of misleading labelling – the Law against Unfair Competition[394] may be applied.[395] On the contrary, in *Ireland*[396] because there is no law that relates directly to labelling fraud in the case of GMOs, the general law dealing with misleading and fraudulent advertisements and labelling is applied exclusively.

Outside the EU, the legislation follows the current that is observable among the EU-Member States.[397] In *Switzerland* compliance with the labelling requirements are backed with penalties on the basis of the national law on GMOs.[398] In *Taiwan*[399] in the case of non-compliance with labelling requirements, an administrative fine or penalty may be imposed. Acts of non-compliance include labelling fraud. Provisions

[389] Cf. Report Ireland, pp. 195 f.

[390] See for example in Germany Sec. 7(2)(4), (3)(3) EGGenTDurchfG (n. 170) in connection with Art. 12(1), 13(1), (2)(a) Regulation (EC) No. 1829/2003 (n. 143) and Art. 4(6)(1) Regulation (EC) No. 1830/2003 (n. 131), Report Germany, p. 119.

[391] Member States shall notify those provisions to the Commission, not later than 18 April 2004 and shall notify it without delay of any subsequent amendment affecting them.

[392] Directive no. 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L109, 6.5.2000, p. 29).

[393] For details on the legislation addressing labelling fraud, see e.g. Report Belgium, pp. 147 f.

[394] Gesetz gegen den unlauteren Wettbewerb UWG (BGBl. 2010 I p. 254).

[395] Report Germany, pp. 119 f.

[396] Report Ireland, p. 197.

[397] See also Report Macau SAR, pp. 440 f.

[398] Art. 17 GTA (n. 171); Report Switzerland, p. 286.

[399] Report Taiwan, p. 418.

relating to fines and penalties exist under the Consumer Protection Act[400] and the Products Labelling Act.[401]

Liability

After having examined questions surrounding the admission of GMOs as well as the subsequent conditions concerning labelling GM products, the natural step is to have a closer look at legislation on liability. It must be addressed since it answers questions as to what consequences the non-compliance with regulation on admission or labelling may lead. Simply put, all the states have in common that their legislations and – in Anglo-American law, case-law – provide in general for civil, administrative and criminal sanctions. Whether law is dealing specifically with liability regarding GMOs or not, every national law has implemented a variety of norms that cannot be enumerated at this point. For further details a reference to the different national reports must therefore suffice.

Administrative

Within the EU both **Regulation (EC) No. 1829/2003** and **No. 1830/2003** stipulate that the EU-Member States shall lay down the rules on penalties applicable to infringements of the regulations' provisions. In particular, the penalties provided for must be effective, proportionate and dissuasive.[402] National legislators may implement additional measures beyond the ones stipulated by the EU according to their legal tradition which also accounts for the considerable variety of liability regimes within the EU. In Germany for example, such penalties have been laid down in an Act implementing the GenTG which provides for both criminal and administrative offences.[403]

As far as **Directive 2001/18/EC** applies, EU-Member States have to "determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive". Again, these penalties must be effective, proportionate and dissuasive.[404]

In Germany it is the GenTG again that lays down both criminal and administrative offences.[405] Italy, with Decreto legge No. 224/2003, inflicts criminal punishments

[400] Art. 56 Consumer Protection Act.

[401] Art. 15 Products Labelling Act.

[402] Art. 45(1), (2) Regulation (EC) No. 1829/2003 (n. 143); Art. 11(1), (2) Regulation (EC) No. 1830/2003 (n. 131).

[403] EGGenTDurchfG. For more details on the individual norms, see Report Germany, pp. 120 ff.

[404] Art. 33(1), (2) Directive 2001/18/EC.

[405] Sec. 38, 39 GenTG. Report Germany, p. 120.

on the breaches regarded as most serious, and sets forth a pecuniary penalty for minor violations.[406]

Additionally, the national legislation adopted in view of the implementation of **Directive 2004/35/EC**[407] on environmental liability with regard to the prevention and remedying of environmental damage, may be relevant as well.[408] However, due to the definition and the thresholds provided for in the definition of environmental damage, it is not likely that GMO-related activities will cause damage in the sense of the environmental liability directive. A reservation is to be made for those national implementation rules that explicitly state the contrary. Austria for instance specifically includes the deliberate release of GMOs into the environment in its federal an regional laws on environmental liability.[409]

Outside the EU, Art. 30 GTA in *Switzerland* is an example for the regulation of liability in context with GMOs. The Act contains its own rules on liability with regard to dealing with GMOs. The general rules on liability in tort or those from the product liability law only apply in a subsidiary manner.[410] The most heated debates between opponents and supporters of genetic engineering concern the liability rules, which explains why these rules are incoherent and ill-conceived.[411] The provisions on GMO-liability differ fundamentally between two scenarios. The first scenario is related to damages incurred prior to the putting into circulation and the second scenario concerns damages that occur after the approved putting into circulation. Relating to the causal connection, the GTA provides a less onerous rule regarding the burden of proof. In principle, it is the responsibility of the person claiming damages to prove a causal connection. If this proof cannot be provided with certainty or if production of proof cannot be expected of the claimant, the court may satisfy itself on the balance of probabilities. The court may also have the facts determined ex officio (Art. 33 GTA). Damage liability is divided into bodily injury (financial loss e.g. as a result of injury) and property damage (financial loss e.g. as a result of damage to property), furthermore the GTA also regulates specifically the environmental damage (Art. 31 GTA).

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[406] Report Italy, p. 239.

[407] Directive 2004/35/EC of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L 143, 30.4.2004, p. 56).

[408] Report Belgium, p. 149. In Belgium the federal legislation is applicable for environmental damage that is caused by the deliberate release into the environment, the transport and placing on the market of GMOs. The regional legislation is applicable when environmental damage is caused by any contained use, including transport, involving GM micro-organisms. See also Report Finland, p. 170.

[409] Cf. § 2 in connection with Annex 1 sec. 10 Bundes-Umwelthaftungsgesetz. In the federal provinces, the Environmental Liability Acts in Burgenland, Lower Austria, Styria and Upper Austria explicitly include the cultivation of GMOs as defined in their respective Acts on Genetic Engineering Precautionary Measures (see section "Inventory" above).

[410] On possibly competing claims see e.g. Christian Hediger, Die Haftungsbestimmungen des Gentechnikgesetzes (Art. 30–34 GTG). Beurteilung und Vergleich mit der Haftungsregelung des deutschen Gentechnikgesetzes (2009), pp. 128 ff., 153, 176 f. Report Switzerland, pp. 286 f.

[411] See Report Switzerland, p. 287, with further references.

A visibly less densely regulated Act can be found in *Norway*, i.e. in its Gene Technology Act (Art. 25 und 23).[412] In *Mexico*, both the general Federal Law on Environmental Liability (LEL) as well as the more specific Law on Biosafety of Genetically Modified Organisms may be applied as possible grounds for liability claims.[413]

Criminal

Many of the national reports indicate that administrative penalties and criminal offences are often regulated in context of a shared legal basis.[414]

The main criminal offences are found within the statutes on GMOs or other key environmental or health statutes; other than that, norms also emanate from general environmental or food law as well as general criminal law.[415]

Civil

Similarly as in the above-mentioned fields of law, in civil law, the regulation on liability is either specifically catered to the matter of GMOs or – if there is no specific regulation thereof – it is to be found in the general norms of the respective national civil codes. As to the specific regulation on civil liability, the legal solutions for losses caused by cross-pollination in neighbouring crops, especially where organic farming is concerned, or commingling is of particular interest.

Within the EU it is not the task of the EU to deal with civil liability for damage, therefore the Union has not introduced specific provisions on this matter.

In *Belgium* in the Walloon and Flemish regional legislation on coexistence, there is an obligation of farmers who cultivate GMOs to compensate the economic losses that may be caused to conventional or organic cultures, including the obligation to buy the harvest that cannot be placed on the market because of (involuntary) admixture.[416] The farmers using GMOs have to pay a contribution to a Fund that will compensate for the economic losses.

In *Germany* as well, civil liability in the field of genetic engineering is governed by the GenTG.[417] According to the GenTG, the operator has to pay damages caused

[412] Report Norway, pp. 256 f.

[413] Report Mexico, pp. 380 f.

[414] E.g. Report Germany, pp. 120 ff.; Report Taiwan, pp. 420 f.; Report Italy, p. 241.

[415] Cf. Report Ireland, p. 211.

[416] Report Belgium, p. 148. In this context cf. the cases of Hoffmann v. Monsanto Canada Inc. as well as the comparably famous case Schmeiser (n. 188), the latter one albeit under reversed premises; Report Canada, pp. 351 ff.

[417] Sec. 32 ff. GenTG (n. 223); Report Germany, p. 121.

by death, bodily injury, injury to health or damage to property which, in turn, are due to traits of an organism which were brought about by the use of genetic engineering. The operator's civil liability does not depend on fault. Furthermore, concerning causality, the GenTG stipulates a rebuttable presumption: If the damage has been caused by GMOs, it is presumed that the damage was caused by such traits of those organisms which were brought about by the use of genetic engineering.[418] In addition, if facts suggest that personal injury or damage to property results from the use of genetic engineering, the operator, on request by the victim, has to provide information on the nature and process of the use of genetic engineering as far as such information is necessary for the purpose of ascertaining whether the operator is liable under the GenTG.[419] In addition to these provisions laid down in special Acts in context with GMOs, the general provisions of civil law explicitly apply as well, though on a subsidiary basis.[420] So the general rule of the Civil Code that the owner of real property may claim appropriate compensation if he or she has to tolerate emissions from neighbouring real property,[421] has been concretised by a special provision in the GenTG for the purposes of coexistence of GM, conventional and organic agriculture.[422] In accordance with this liability framework, GM farmers have to compensate conventional or organic farmers if the latter are prohibited from placing their products on the market or if they have to label their products indicating the presence of GM material or if they are prevented from using a label which could have been affixed to their products according to the rules related to their method of production because of GM emissions.[423]

In the *Austrian* Civil Code,[424] there is a provision similar to the one stipulated in the German Civil Code, whilst, however, in Austria there is – contrary to the legal situation in Germany – no adjudicated court ruling to date on whether incidents involving GMOs actually fall under the scope of this provision.[425] The liability rules stipulated by the Act on Genetic Engineering (Gentechnikgesetz, GTG)[426] are conceived as civil liability and encompass in its § 79 k a provision on the liability for the cultivation of GMOs that has been drafted particularly with a view to the agricultural use.[427] According to this provision, the owner or the authorised user of

[418] Sec. 34(1) GenTG (n. 223).

[419] See Sec. 35 GenTG (n. 223).

[420] 37(3) German GenTG (n. 223).

[421] Cf. Sec. 906(2)(2) BGB.

[422] See Sec. 36a GenTG (n. 223). See Jürgen Kohler, Schadensausgleich in Fällen des §36a Gentechnikgesetz, NuR 2005, p. 566; Gerhard Wagner, Nachbarhaftung für gentechnische Immissionen, Versicherungsrecht 2007, p. 1017.

[423] The recovery of damages requires that the GM immissions occurred despite the fact that the GM farmer has complied with the standards of good professional practice; Sec. 36a(2) GenTG (n. 223).

[424] Cf. § 364(2) ABGB and § 79 h GTG.

[425] Daniela Nowotny, p. 419 (n. 26).

[426] Cf. §§ 79a ff. GTG.

[427] Ferdinand Kerschner, Neue Gentechnikhaftung in der Landwirtschaft (§§ 79k-m GTG), in: Roland Norer/Anton Reinl (eds.), Haftungsfragen in der Land- und Forstwirtschaft (2005), p. 37,

agricultural farming land may prohibit any emission of a farmer cultivating GMOs on the adjacent land insofar as these emissions exceed normal local levels and significantly interfere with the usual use of the land. The neighbour is held liable for the economic loss, thus he must compensate the economic loss as well as the costs for the restoration of the environment. The legislator recurs to a rebuttable presumption of causal connection. If the landowner claiming to have incurred damages can furnish prima facie evidence that a specific action of his neighbour was likely to lead to the emission, it is presumed that the emission was caused by this action. Before seizing the court, a hearing by conciliation body must be scheduled.[428]

In *Italy*, Decreto legge 279/2004 required all farmers who cultivated transgenic crops to lay down their plans for growing GM crops in a business plan in order to ensure accordance with the regional coexistence plan. Its Art. 5 determines that whoever suffers damage is entitled to a compensation by the farmer using GMOs without complying with the regional coexistence plan and with his own business management plan.[429] It is a form of liability in tort, and fault-based, although it leads to an inversion of the burden of proof: It is the person causing the damage who bears the burden of proof that he/she observed the measures laid out in the regional plans and business management plan. The farmer's liability is wholly excluded if the farmer used seeds certified by the public authorities that are additionally declared free of GMOs by the supplier. In this case the liability for damage caused is borne by the suppliers of the technical means of production and by the other operators of the primary production chain.

In this context, once more the Environmental Liability Directive 2004/35/EC must be mentioned as *Ireland*[430] for instance implements it within the framework of its national civil law.

Outside the EU, the *USA* opted for a regulatory framework for GMOs and GM foods that "does not assign liability for damages possibly caused by their cultivation and use." The development of GMOs is subject to "the provisions of federal laws and regulations that govern authorisation"; non-compliance may lead to penalties established by statute. Furthermore, another important legal aspect is contract obligations, meaning that producers who cultivate GM crops are contractually obliged to observe certain provisions dictated by the crop developer (most commonly provisions on intellectual property rights). This sometimes entails the enforcement of "these rights by litigation against producers who violate contract obligations and others whose crops contain patented varieties, even unintentionally."[431] Some examples of liability indicate that controversies so far have focussed on release of unauthorized varieties rather than issues of food safety.

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and RdU 2005, p. 112; Ferdinand Kerschner/Eva Claudia Lang/Gabriele Satzinger/Erika Wagner, Kommentar zum Gentechnikgesetz (2007), §§ 79a ff.

[428] § 79 m GTG.

[429] Report Italy, p. 241.

[430] Report Ireland, p. 203.

[431] The quotes in this paragraph are all taken from Report USA, pp. 329 ff.

Product Liability

Within the EU the national regulations on the implementation of **Directive 85/374/EEC** on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products[432] are to be applied.[433] In general GMOs can fall under the scope of this piece of legislation if damage is caused by a defective product. In principle, a product is found defective when it does not provide the safety which a person is entitled to expect. There is, however, no specific type of legal liability regarding GM products.

In this context, one norm is to be highlighted particularly: According to Art. 7(e) Directive 85/374/EEC, the producer will not be held liable if he can prove "that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered" ("development risk"). Especially in the case of GMOs, it is conceivable that GM food did not present any risk at the time when it was put into circulation, which does, however, not wholly exclude the possibility that new scientific evidence hints at a possible harmfulness of GM food. Thus, if there are national rules in the Member States providing an exoneration from liability in case of scientific proof for the disadvantageous nature of GM food, then the producer will not be liable for damages caused by his product.[434]

In *Germany* the scope of the Law on Product Liability[435] encompasses GM products including agricultural GM products.[436] However, the GenTG modifies product liability under the ProdHaftG to a certain extent. The reasoning – albeit not an uncontested one – behind this modification is the fact that the producer of the seed (i.e. the developer of the seed and thus holder of the respective authorisation) rather than the farmer (as the user of the GM seed) shall be subject to civil liability under the ProdHaftG. Manufacturers of GM products can be held liable even if the product's defect could not be diagnosed by the state of science and technology at the time when the product was placed on the market.[437]

In *Italy*, Art. 122 of the national Consumer Code may lead to the result that consumers using food which is clearly indicated as having undergone genetic modification are deemed to have spontaneously exposed themselves to the "danger" emanating from GMOs. The producer should be exonerated from any liability since in this case, the label has the effect of passing on the risk of potential damages to

[432] Directive No. 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

[433] In this sense Report Belgium, p. 150; Report Ireland, p. 209 where apart from the Liability for Defective Products Act 1991 the common law may be applied in addition.

[434] Report Italy, p. 243.

[435] Product Liability Act, Gesetz über die Haftung für fehlerhafte Produkte (Produkthaftungsgesetz – ProdHaftG) (BGBl. 1989 I p. 2189).

[436] Report Germany, p. 123.

[437] Sec. 37(2)(2) GenTG (n. 223).

health to the consumer. The Italian Report states a shift of responsibility from the producer to the consumer.[438]

Outside the EU the regulation to be found is largely comparable to the general provisions on product liability, usually their scope extends to foodstuff as well.[439]

Switzerland for instance enacted a specific provision on liability in context with GMOs: Art. 30 GTA introduces a tightened product liability in para. 4–6.[440] A compensation is due if the organisms are defective, i.e. if the damage occurred as a result of the modification of genetic material. This regulation essentially corresponds with the respective EU law and its implementation in the Member States. Where there is no special liability regime, it appears extremely difficult to hold the State, the bioengineering industry or neighbouring farmers liable for damages sustained by GMOs.[441]

Summary

The fast emergence of genetic technology has defied legislators around the world. However, as the national reports show, the states were up to the challenge: They have closely been following the development of the technology and have provided legal answers, i.e. regulations governing the use of GMOs. In doing so, legislators have both scientific findings and public debate in mind. This explains why there are states that consider GMOs useful and sometimes even encourage its use actively. Other states are neutral and leave GMO regulation essentially up to the market and its players. Some countries take on a more sceptical approach that is induced by its citizens. Surveys show that especially European countries tend to be critical about GM food; suspicions towards genetic engineering are relatively high compared to, namely, the USA or Canada.

However critical genetic engineering may be viewed, an important argument in favour of the use of this new technology is the concern for **food security and the right to food**. GM products are seen as a mean to secure the food supply for a steadily growing world population. Thus, GM food may be one of the answers to the claim of food security, understood as referring to the availability of food including the securing of one's access to food. The concept of food security is closely intertwined with **food safety**, which is defined as relating to human health, i.e. whether food is safe for consumption by humans or whether it might threaten human health. This factor often leads to public debates because GM food seems to be considered to possibly bear unintended long-term consequences or various risks for food safety. It is in this area of opposed concerns that national legislators must make their choices when lining out the legal framework as well as the specific norms regulating admission, labelling and liability in context of GMOs.

[438] Report Italy, p. 243.

[439] Report Canada, pp. 350 ff.; Report Macau SAR, pp. 443 f.

[440] Report Switzerland, pp. 289 f.

[441] Assessment according to the Report Canada, p. 356.

On international level, there are various **treaties and norms** that regulate questions touching on the issue of genetic technology. Important are namely the ICESCR, the International Treaty on Plant Genetic Resources for Food and Agriculture, the influence of the Codex Alimentarius Commission with its soft law, the Cartagena Protocol on Biosafety and, of course, in the context of the WTO the SPS Agreement as well as the TBT Agreement and the GATT. On EU level, there is a general legal framework for genetic engineering and specifically addressing GM food, consisting of various directives and regulations governing the authorisation or labelling of GMOs. Additionally, pertinent rules may also be found in the general legal framework for food. Systematically speaking, the legal framework concerning the use of GMOs in the EU might be looked upon as being anchored somehow in between general genetic engineering law and general food law. Finally, on national level, the legal **fragmentation of legal sources and competences** of authorities continues since the states have enacted rules on genetic engineering for food production, too.

This fragmentation can also be noted for the questions concerning the admission of GM products. On the European continent, there are various **legal restrictions for genetic engineering**, they are fewer in the USA or Canada. Over the past, individual states (e.g. Italy or Austria) have repeatedly prohibited specific admissions of GM products on their territory, sometimes even against an admission issued according to EU law, thus accepting a conflict between national and EU law. Of such nature are the cases that often led to recourses to the European Court of Justice (ECJ) or even to WTO-Panels due to an infringement to the SPS Agreement. Generally, national **prohibitions** are only permitted by EU and WTO law in accordance with their regulation, e.g. through the operation of a **safeguard clause** in situations where there is a proven risk to the environment and/or human health. Thus, general **moratoria** are no longer part of the EU-Member States' strategies, only Switzerland knows a de jure and de facto moratorium.

In order to control and restrict the use of GMOs, states generally recur to other measures, e.g. by invoking safeguard measures. These provisions – set forth in EU law – are, however, usually interpreted conservatively, e.g. closely following the text. The Member States have to put forward evidence that the level of protection is not satisfactory, which means they must disprove the outcome of the prior **authorisation procedure** and conditions imposed. It is therefore difficult for the Member States to recur to safeguard clauses. Another option is the creation of **"GMO-free zones"** which can occur on a voluntary, contractual or a legally binding basis. Within the EU however, new scientific evidence for risks to human health and the environment is conditional to the attempt to install legally binding "GMO-free zones".

GMO-free zones can only be ensured if there are measures preventing commingling. The most common measure can be pinned down to the term of **coexistence**. Coexistence means the simultaneous cultivation of different crops side by side; with regard to genetic engineering the coexistence of conventional, organic and GM crops. Thereby, in principle farmers can choose which crops they want to cultivate. Thus, also the consumers will be enabled to choose between GM food and food that is free of GMOs.

When it comes to **admission** of GMOs, practically every state participating in this comparative report has legislated on the matter of GMOs in food production. Foodstuffs with GMOs require an **authorisation for being put into circulation**. In most cases, the regulation follows a step-by-step-principle. Rules of procedure, often very detailed ones, provide a backbone for the coordination between different authorities, the involvement of advisory committees or the documentation requirements. Within the EU for the Member States the admission is primarily governed by EU law which is complemented by national law as far as it concerns procedural aspects. The authorisation process commences at a national level, but the risk assessment and decision are made at the EU level. EU law provides that GM food and feed may be placed on the market on the basis of an authorisation only.

Closely related to authorisations of GMOs are the **threshold values** that define within which limits traces of genetic modifications are legally irrelevant. Within the EU, such threshold values either occur in the form of an exemption from being subjected to an authorisation (authorisation thresholds) or as derogation from labelling obligations (labelling thresholds). There are special standards to be taken note of for organic farming and for seed. But there is no threshold for products regarding the maximum level of GMOs in them (or regarding the use of GMOs in producing them). Outside the EU, threshold values are widely unknown except where they are deduced from EU law for countries interacting economically and legally with the EU.

Depending on the observance of thresholds or other legal provisions, GM products, regulations are often subject to **labelling** prescriptions and, following the violation thereof (labelling fraud, misleading labelling), sanctions. Within the EU, labels declaring food free of GMOs is not prohibited. By contrast, products containing GMOs must be declared as such when they exceed the relevant thresholds. EU member states or states outside the EU often know similar regulation on labelling, additionally, there often are provisions for labels declaring food free of GMOs. By contrast, in other countries such as Canada or on the federal level in the USA, there are no specific rules on labelling, sometimes with the exception of provisions concerning organic production.

Non-compliance with regulation on the admission or labelling of GMOs may lead to civil, administrative and criminal sanctions. All states stipulate provisions on **liability**, sometimes specifically catered to GMOs, sometimes in context with general civil, administrative or criminal legislation. Within the EU, the regulations pertinent to genetic engineering in food production usually requires the Member States to lay down the rules on penalties applicable to infringements of the provisions. The penalties must be effective, proportionate and dissuasive. National legislators may implement additional measures beyond the ones stipulated by the EU according to their legal tradition which accounts for the considerable variety of liability regimes within the EU. When it comes to civil liability, the legal solutions for losses caused by cross-pollination in neighbouring crops, especially where organic farming is concerned, or commingling are of particular interest. The EU has not introduced rules for damages of this kind, the Member states and states outside the EU however often have. In context with regulations on coexistence for instance, they stipulate

rules on the consequences for involuntary admixture which is of particular relevance for organic farming or damages for the environment. In general, GMOs can also fall under the scope of regulation on product liability.

The **wide array of regulation** on GMOs in food production reflects the political and social discussions within the legal communities. Genetic engineering remains controversial, especially in Europe. This explains the more cautious approach the EU, its Member States and other European countries have adopted towards GMOs. The research presented by the national reporters corroborates the assumed bifurcation between European legislation on the one hand and legislation of non-European countries on the other hand. However, there seems to be a cautious trend towards more acceptation of genetic technology for food production in the EU, which does not necessarily mean that the Member States agree, quite on the contrary as the examples of Italy or Austria show where there is a fear of disadvantageous effects on food safety or the environment. Other states have embraced the advantages GMOs are said to convey, e.g. improved yields and a contribution to food security, and have thus adopted a more liberal approach. In the end, it all comes down to the fundamental questions the emergence of a technology raises. The answers as to how the law should respond to these questions are formed by public debate, social opinion and scientific evidence. At the end of the day, it is the legislators' task to pour those factors into laws and regulations.

Part I
National Reports – EU

Chapter 2
Genetic Technology and Food Security: Country Report – Germany

Hans-Georg Dederer

In 2013 and 2014, no GM plants were released into the environment in Germany, neither for research nor for commercial purposes. Political as well as legal grounds may have contributed to this development. In fact, the German public tends to be much more critical about agricultural biotechnology than the EU average. Politicians seem to have bowed to the public's distrust against GMOs. Both the executive and the legislature have exercised almost any margin of discretion left by EU law to the Member States in order to strangle GM plant cultivation. Examples include the Federal Ministry of Agriculture's order suspending the cultivation of the GM variety MON810 and strict liability provisions which prompted the German Farmers' Association to advise every farmer against GM crop cultivation.

General Information

Use of GMO in Food Production

Facts and Figures About the Use of GMOs

In Germany, the use of genetically modified organisms (GMOs) is virtually confined to so-called 'contained use', i.e. GMOs are used in laboratories, growth-rooms, glasshouses, animal units or industrial plants only. Throughout Germany, there exist several thousand contained use facilities. Statistics are provided by the

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German States, i.e. the 'Länder',[1] which are competent for the implementation and enforcement of the federal Law on Genetic Engineering (Gentechnikgesetz – GenTG)[2] as far as it concerns the contained use of GMOs.[3] In Bavaria, e.g., there exist currently 796 contained use facilities, of which 551 can be attached to public operators (e.g., universities) and 236 to private operators (e.g., Max-Planck-Institutes, major research institutions, firms).[4] In 582 contained use facilities class 1/safety level 1-activities[5] are carried out, whereas class 2/safety level 2-activities are carried out in 202 facilities and class 3/safety level 3-activities in only 12 facilities.[6]

In 2013, no GM plants were released into the environment, neither for research nor for commercial (e.g., agricultural) purposes.[7] The only field trial which took place in Germany in 2013 concerned bacteria (Rhodococcus equi: attenuated vaccine line), i.e. a genetically modified micro-organism (GMM).[8] The bacteria were released into the environment on the municipal territory of Grabow in Mecklenburg-Vorpommern on a parcel of 1800 m^2. In fact, since 2007, the number of field trials with GM plants has steadily and sharply declined.[9] On the other hand, cultivation of Bt corn (MON810) increased slowly but steadily for 4 years between 2005 (342 ha) and 2008 (3173 ha).[10] However, it ended abruptly in 2009 due to a safeguard measure adopted by the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit – BVL).[11]

[1] See http://www.lag-gentechnik.de/index.html

[2] Gesetz zur Regelung der Gentechnik (BGBl. 1993 I p. 2066), last amended by law of 7 August 2013 (BGBl. 2013 I p. 3154).

[3] Sec. 31(1) GenTG.

[4] http://www.stmug.bayern.de/umwelt/gentechnik/bayern/anlagen.htm

[5] Concerning the classification of contained uses in four classes or safety levels respectively see Art. 4(3) Directive 2009/41/EC (with regard to classes) and Sec. 7(1)(1) GenTG (with regard to safety levels).

[6] http://www.stmug.bayern.de/umwelt/gentechnik/bayern/anlagen.htm

[7] http://apps2.bvl.bund.de/stareg_web/showflaechen.do; http://apps2.bvl.bund.de/stareg_visual_web/localeSwitch.do?language=de&page=/data.do

[8] http://apps2.bvl.bund.de/stareg_web/showflaechen.do?year=2013

[9] http://www.transgen.de/anbau/deutschland/1714.doku.html

[10] http://www.bvl.bund.de/DE/06_Gentechnik/01_Aufgaben/02_ZustaendigkeitenEinzelneBereiche/04_Standortregister/Auswertung_Stareg/gentechnik_standortregister_HG_Auswertung_Stareg_node.html

[11] See infra at section "Restriction of GMO" (in and at fn. 207–211).

Public Opinion on GMOs

According to a Eurobarometer survey of 2010,[12] 95 % of respondents in Germany have heard of GM food (EU27 average: 84 %).[13] 74 % of respondents in Germany affirm that they have also talked with others about GM food before (EU27 average: 66 %).[14] However, only 44 % of respondents in Germany have searched for information on GM food (EU27 average: 38 %).[15] 69 % of respondents in Germany think that GM food is neither good for them nor their families (EU27 average: 54 %).[16] Only 41 % agree (compared to 46 % who disagree) that GM food helps people in developing countries (EU27 average: 43 % who agree, 37 % who disagree).[17] 72 % of respondents in Germany opine that GM food is not safe for future generations (EU27 average: 58 %).[18] As many as 75 % of respondents in Germany are of the opinion that GM food benefits some people but puts others at risk (EU27 average: 57 %).[19] Almost in line with the EU27 average of 70 %, 69 % of respondents in Germany agree that GM food is fundamentally unnatural.[20] 78 % of respondents in Germany admit that GM food makes them feel uneasy (EU27 average: 61 %).[21] Only 17 % of the respondents in Germany (EU27 average: 22 %) agree and 74 % disagree (EU27 average: 59 %) that GM food is safe for one's health.[22] In fact, 71 % of respondents in Germany (EU27 average: 66 %) are worried about GMOs in foods and beverages.[23] Similarly, only 21 % of the respondents in Germany (EU27 average: 23 %) agree that GM food does no harm to the environment whereas 64 %

[12] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341).

[13] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 14.

[14] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 16.

[15] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), P. 17.

[16] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 21.

[17] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 22.

[18] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 24.

[19] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 25.

[20] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 26.

[21] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 27.

[22] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 29.

[23] European Commission (ed.), Eurobarometer 73.5: Risiken im Lebensmittelbereich, 2010, p. 2.

disagree (EU27 average: 53 %).[24] Accordingly, only 20 % of the respondents in Germany (EU27 average: 23 %) believe that the development of GM food should be encouraged whereas 72 % (EU27 average: 61 %) think it should not.[25]

Thus, public awareness of GM food is exceptionally high in Germany. Astonishingly, a significant majority of the public seems to see no need to actively catch up on GM food, though. The German public appears to be confident about being able to assess the pros and cons of GM food, albeit, perhaps, on a thin informational basis. Although the Eurobarometer survey "reveals an overall suspicion of GM foods amongst the European public",[26] the German public tends to be much more critical about GM food than the EU average. The perception that GM food is likely to pose serious health and environmental risks is significantly more widely spread among people in Germany than among people in other EU Member States. Correspondingly, according to an opinion poll carried out by Forsa,[27] 82 % of the respondents in Germany consider the label "ohne Gentechnik" ("without genetic engineering") wise,[28] *i.e.* a vast majority of the German public is highly interested in consumer information on whether products are GM free or not.

Position of the Government on GMOs

The Federal Government (*i.e.* the 'Bundesregierung') cannot but acknowledge that genetic engineering is a highly contested technology.[29] Nevertheless, with regard to the impact of agricultural biotechnology on secure food supply world-wide, the government takes a remarkably more differentiated view on GM food and their risks and benefits than the German public.[30] On the other hand, perhaps due to the German public's strong suspicions of GM food, the government seems to be quite careful in avoiding a clear cut position pro or contra GM food as far as it concerns global food security.

Thus, the Federal Government refers to scientific studies according to which GM plants can contribute to global food security but acknowledges at the same time that there are other studies which suggest that this question depends on the local context

[24] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 30.

[25] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 32.

[26] European Commission (ed.), Eurobarometer 73.1: Biotechnology, 2010 (Special Eurobarometer 341), p. 18.

[27] Gesellschaft für Sozialforschung und statistische Analysen mbH.

[28] http://www.gentechnikfreie-regionen.de/hintergruende/studien/umfragen.html

[29] BT-Drs. 17/8819, p. 5.

[30] See BT-Drs. 17/8819 of 1 March 2012, providing the Federal Government's answer to an enquiry made by some Members of Parliament (MPs) of the Green Party (Bündnis 90/Die Grünen). The questions raised by the MPs concerned the Federal Government's attitude towards the relevance of agro genetic engineering and the EU's agricultural policy for global food security.

within which GM plants are used.[31] According to the government, the contribution of GM crops to food security has not been settled yet.[32] Against the background of climate change, the government believes that drought resistant plants will be of particular importance.[33] In this regard, the government explicitly refers to GM corn (MON87460).[34] With regard to growing demand for meat and dairy products due to significantly increasing wealth worldwide GM feed can contribute to food security globally.[35] Moreover, the government points to studies according to which global prices for corn, soybean, cotton and rape seed could have been much higher and global crop production smaller and less stable if GM plants had not been used.[36] Finally, the government intends to support international agricultural research but will not focus exclusively on organic agriculture.[37]

These official statements of the Federal Government were, and are as a rule, prepared by public officials of the competent federal ministries who, in turn, relied on scientific expertise. Thus, these official governmental statements have to be distinguished from the political position of the political parties forming the coalition government on the federal level. Interestingly enough, coalition agreements, which form the political basis of an incoming multi-party government, have taken up the issue of GMOs. The balance between risks and benefits of GMOs and thus the regulatory approach during the election period depended, of course, on the political "colour" of the coalition partners. Thus, *e.g.*, the coalition agreements into which Social Democrats and Greens entered into in 1998[38] and 2002[39] attached more importance on the risks and socio-economic aspects associated with GMOs whereas the coalition agreement adopted in 2009 by the Christian Democrats and the Liberals intended to enhance the use of GMOs.[40] After elections to the Federal Parliament (*i.e.* the 'Bundestag') have been held on 22 September 2013, the political position of the incoming government constituted by Christian Democrats and Social Democrats is again more cautious vis-à-vis agricultural genetic engineering in general and GM food in particular. Although "Biotechnologie" (biotechnology) is identified as a "Leitmarkt" (leading market),[41] the governing parties accept the

[31] BT-Drs. 17/8819, p. 4.

[32] BT-Drs. 17/8819, p. 5.

[33] BT-Drs. 17/8819, p. 4.

[34] BT-Drs. 17/8819, p. 4.

[35] BT-Drs. 17/8819, p. 6.

[36] BT-Drs. 17/8819, p. 7.

[37] BT-Drs. 17/8819, p. 9.

[38] Aufbruch und Erneuerung – Deutschlands Weg ins 21. Jahrhundert. Koalitionsvereinbarung zwischen der Sozialdemokratischen Partei Deutschlands und BÜNDNIS 90/DIE GRÜNEN, 1998, p. 18–19.

[39] Koalitionsvertrag 2002–2006: Erneuerung – Gerechtigkeit – Nachhaltigkeit, 2002, p. 47.

[40] Wachstum. Bildung. Zusammenhalt. Koalitionsvertrag zwischen CDU, CSU und FDP, 17. Legislaturperiode, 2009, p. 48–50.

[41] Deutschlands Zukunft gestalten. Koalitionsvertrag zwischen CDU, CSU und SPD, 18. Legislaturperiode, 2013, p. 19.

population's reservations towards "Grüne Gentechnik" (green genetic engineering).[42] In addition, the coalition partners advocate compulsory labelling of animal products from animals which have been fed with GM plants.[43] Furthermore, they promise to abide by the zero tolerance for GM traces from non-authorized GMOs in food and to stick to purity of seed.[44]

The political view of the governments of the 'Länder' may differ considerably from the Federal Government's position. Thus, some 'Länder' governments may be significantly more critical than the government on the federal level. What is more, negative attitudes towards genetic engineering may cut cross political lines. This holds currently true, *e.g.*, for Bavaria and Lower Saxony. In 2011, *e.g.*, the Bavarian Minister for Environment and Health, a Christian Democrat, officially declared in a press release that it had to be ensured that Bavaria remains free of GM crop cultivation permanently.[45] In Lower Saxony, according to press coverage of March 2013, the newly inaugurated government, built on a coalition agreement between Social Democrats and Greens, banned genetic engineering laboratories from schools.[46] Other 'Länder' governments take up a more benevolent, even sympathetic stance vis-à-vis genetic engineering. In 2005/2008, *e.g.*, the government of Saxony-Anhalt (unsuccessfully)[47] sought judicial review of several amendments to the GenTG which seriously impeded GM crop cultivation in Germany.

It is not without piquancy that, in 2009, the Federal Ministry of Food, Agriculture and Consumer Protection (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz – BMELV), which was then headed by a Christian Democrat from Bavaria, ordered the competent authority, *i.e.* the BVL,[48] to adopt a safeguard measure suspending the market authorisation for MON810 (Bt maize) as far as it concerned cultivation. This safeguard measure was bluntly rejected by the BVL's own expert body, *i.e.* the Central Committee on Biological Safety (Zentrale

[42] Deutschlands Zukunft gestalten. Koalitionsvertrag zwischen CDU, CSU und SPD, 18. Legislaturperiode, 2013, p. 123.

[43] Deutschlands Zukunft gestalten. Koalitionsvertrag zwischen CDU, CSU und SPD, 18. Legislaturperiode, 2013, p. 124, 127.

[44] Deutschlands Zukunft gestalten. Koalitionsvertrag zwischen CDU, CSU und SPD, 18. Legislaturperiode, 2013, p. 124.

[45] Bayerisches Staatsministerium für Umwelt und Gesundheit, Pressemitteilung Nr. 63/11, 04. Mai 2011.

[46] http://www.spiegel.de/schulspiegel/wissen/gentechnik-unterricht-in-niedersachsen-rot-gruen-macht-schullabor-dicht-a-886140.html

[47] See BVerfGE 128, 1; very critical review by Hans-Georg Dederer, Verfassungskonforme Übermaßregulierung der „Grünen Gentechnik" – Zum Urteil des BVerfG vom 24.11.2010 – 1 BvF 2/05, Juristische Ausbildung 2012, p. 218; Winfried Kluth, Das Gentechnik-Urteil, 2012.

[48] The BLV is a federal agency subject to the BMELV and competent for the implementation and the enforcement of the GenTG as far as it concerns the deliberate release of GMOs into the environment or the placing on the market of products containing or consisting of GMOs (cf. Sec. 31(2) GenTG). Concerning the BVL's competence in the field of GM food law see infra at section "Implementation and enforcement, controlling regime" (in and at fn. 365–369).

Kommission für die Biologische Sicherheit – ZKBS) which explicitly stated that the cultivation of the GM variety MON810 did not pose environmental risks.[49]

Food Security

The term 'food security' has to be distinguished from the term 'food safety'. Food safety relates to human health, *i.e.* whether food is safe for consumption by humans or whether it might threaten human health. Thus food safety is concerned with "health-based consumer protection".[50] In Germany, this is the mission of the BVL.[51] Food safety is also the very purpose of the Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch – LFGB).[52,53] The LFGB does not define the notion 'food safety', though.

'Food security' means that the population at large has access to sufficient food. More specifically, according to the Committee on World Food Security (CFS), an intergovernmental forum within the UN system,[54] "[f]ood security exists when all people, at all times, have physical, social and economic access to sufficient safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life."[55] German law does not provide for a legal definition of 'food security'. What is more, the notion of 'food security' is mentioned only occasionally, *e.g.*, in the Basic Law (Grundgesetz – GG),[56] *i.e.* in the federal constitution,[57] and in the Bavarian Constitution (Bayerische Verfassung – BV).[58,59]

Interestingly, food security is not directly or explicitly addressed by the German Federal Government as a problem Germany should be concerned about within its own borders. Problems concerning food security are considered to be of importance to developing countries. Therefore, food security is dealt with as a matter of

[49] Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Stellungnahme der ZKBS zur Risikobewertung von MON810 – Neue Studien zur Umweltwirkung von MON810, Kurzfassung, Az. 6788-02-13, 7 July 2009.

[50] http://www.bvl.bund.de/EN/01_Food/lm_food_node.html

[51] http://www.bvl.bund.de/EN/01_Food/lm_food_node.html

[52] Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (BGBl. 2013 I p. 1426), last amended by law of 7 August 2013 (BGBl. 2013 I p. 3154).

[53] Sec. 1(1)(1) LFGB.

[54] See Art. III(9) FAO Constitution.

[55] http://www.fao.org/cfs/en/

[56] Grundgesetz für die Bundesrepublik Deutschland (BGBl. 1949 p. 1). For a quasi-official translation into English see http://www.gesetze-im-internet.de/englisch_gg/basic_law_for_the_federal_republic_of_germany.pdf

[57] See Art. 74(1)(17) GG which confers concurrent legislative powers upon the Federation in the area of "ensuring the adequacy of food supply".

[58] Verfassung des Freistaates Bayern (GVBl. 1946 p. 333).

[59] See Art. 83(1) BV which provides that food security facilities are within the realm of municipal self-government.

development policy.[60] The question whether and to what extent GMOs could play a decisive role in ensuring food security in developing countries has been carefully circumvented by the Federal Government.[61]

Legal Superstructure

Legal Superstructure Concerning Food Security

Public International Law

Germany is a party to both the International Covenant on Civil and Political Rights (ICCPR)[62] and the International Covenant on Economic, Social and Cultural rights (ICESCR)[63] as well as to the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW)[64] and the Convention on the Rights of the Child (CRC).[65] All these treaties have a bearing on food security albeit to a different degree.

Art. 11(1)(1) ICESCR guarantees the "right … to … adequate food" and Art. 11(2) ICESCR provides for the "right … to be free from hunger". According to General Comment 12 of the Committee on Economic, Social and Cultural Rights (CESCR), "the core content of the right to adequate food implies: The availability of food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances, and acceptable within a given culture".[66] Art. 12(1) ICESCR and Art. 24(1)(1) CRC which enshrine the "right … to the enjoyment of the highest attainable standard of physical and mental health" are closely related to food security as well.[67] Art. 24(2)(c) CRC is even more explicit obliging States to "take appropriate measures … to combat … malnutrition … through the provision of adequate nutritional foods". Additionally, due to Art. 6(1)(1) ICCPR, *i.e.* the "right to life", the government is obliged to protect[68] the individual, *e.g.*, from starvation. In addition, the General Assembly (GA) of the United Nations has explicitly

[60] See, e.g., http://www.bundesregierung.de/Webs/Breg/DE/Themen/Entwicklungspolitik/3-Armut-bekaempfen/ernaehrung/_node.html; http://www.bundesregierung.de/Webs/Breg/DE/Themen/Entwicklungspolitik/4-LaendlicheEntwicklung/ernaehrungssicherheit/_node.html

[61] See BT-Drs. 17/8819 and supra at section "Use of GMO in food production" (in and at fn. 29–37).

[62] UNTS vol. 999, p. 171; BGBl. 1973 II p. 1543.

[63] UNTS vol. 993, p. 3; BGBl. 1973 II p. 1570.

[64] UNTS vol. 1249, p. 13; BGBl. 1985 II p. 648.

[65] UNTS vol. 1577, p. 3; BGBl. 1992 II p. 121.

[66] http://www.unhchr.ch/tbs/doc.nsf/0/3d02758c707031d58025677f003b73b9

[67] *Cf.* General Comment No. 14 (2000) of the CESCR.

[68] See Art. 6(1)(2) ICCPR.

recognized the right to water.[69] The GA's resolution on "The human right to water and sanitation" is not legally binding, though. Albeit UN Member States have to pay due respect to that resolution. According to the CESCR, the right to water can be derived from Art. 11(1), 12(1) ICESCR.[70] Art. 14(2) CEDAW[71] and Art. 24(2)(c) CRC[72] are even more explicit.

The ICCPR, the ICESCR, the CEDAW and the CRC have been incorporated into the domestic sphere by means of federal laws[73] giving parliamentary consent to the conclusion of these treaties.[74] In addition, the treaty provisions which have been just mentioned above are also directly applicable within the German domestic legal order except for Art. 14(2) CEDAW, Art. 24(2)(c) CRC which are not self-executing.

Germany is also a Member State of the Food and Agriculture Organization (FAO). According to the FAO's Constitution,[75] the FAO Member States are expected to take "separate or collective action" for the purpose of "ensuring humanity's freedom from hunger".[76]

Regional human rights instruments are, of course, applicable as well. Germany is a contracting party to the Convention for the Protection of Human Rights and Fundamental Freedoms, *i.e.* the European Convention on Human Rights (ECHR).[77] Under the ECHR, Germany has the duty to protect the "right to life"[78] and the "enjoyment of [one's] possessions",[79] *i.e.* the right to property. Like the aforementioned universal human rights instruments the ECHR has been incorporated into the domestic sphere by a federal law.[80]

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[69] A/Res/64/292.

[70] General Comment No. 15 (2002) of the CESCR.

[71] States shall ensure the right to "enjoy adequate living conditions, particularly in relation to … water supply".

[72] States shall "combat disease and malnutrition … through the provision of adequate nutritious foods and clean drinking-water".

[73] Concerning the ICCPR see BGBl. 1973 II p. 1534, concerning the ICESCR see BGBl. 1973 II p. 1570, concerning the CEDAW see BGBl. 1985 II p. 648, and concerning the CRC see BGBl. 1992 II p. 121.

[74] *Cf.* Art. 59(2)(1) GG and BVerfGE 111, 307, at 316–217 = BVerfG, Order of 14 October 2004, 2 BvR 1481/04, para. 31 (http://www.bverfg.de/entscheidungen/rs20041014_2bvr148104en.html).

[75] BGBl. 1971 II p. 1033.

[76] Preamble of the FAO Constitution.

[77] BGBl. 2010 II p. 1198.

[78] Art. 2(1)(1) ECHR.

[79] Art. 1(1)(1) of the (first) Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms (BGBl. 2010 II p. 1198).

[80] See BGBl. 1952 II p. 685.

European Union Law

In addition, the Charter of Fundamental Rights of the European Union (ChFR)[81] provides for individual rights some of which have a bearing on food security as well. *E.g.*, both "life"[82] and "physical integrity"[83] of the individual as well as his or her "property"[84] have to be protected. Farmers enjoy the "freedom to conduct a business".[85] Furthermore, a "high level of human health protection"[86] as well as a "high level of consumer protection"[87] shall be ensured.

The ChFR is primarily addressed to the EU and its organs. The EU Member States have to comply with the ChFR "only when they are implementing Union law".[88] This phrase has been construed by the Court of Justice of the European Union (ECJ) meaning that the ChFR is applicable to Member States "where national legislation falls within the scope of European Union law … . The applicability of European Union law entails applicability of the fundamental rights guaranteed by the Charter".[89]

In fact, the EU has broad legislative powers in the fields of agriculture and fisheries.[90] Productive agriculture and fisheries are, of course, essential for food security in the EU and its Member States. In addition, the EU may adopt legislation for the purpose of the functioning of the internal market.[91] An essential element of the concept of the internal market is the free movement of goods,[92] which extends also to food. Food security depends on access to, and availability of, sufficient nutritious food which, in turn, warrants the unhampered circulation of food.

[81] OJ C 303, 14.12.2007, p. 1.

[82] Art. 2(1) ChFR.

[83] Art. 3(1) ChFR.

[84] Art. 17 ChFR.

[85] Art. 16 ChFR.

[86] Art. 35(2) ChFR.

[87] Art. 38 ChFR.

[88] Art. 51(1) ChFR.

[89] ECJ, Case C-617/10, Åkerberg Fransson, para. 21.

[90] See Art. 38 et seq. of the Treaty on the Functioning of the European Union (TFEU) (OJ C 115, 9.5.2008, p. 47).

[91] Art. 114(1) TFEU. Both competences, i.e. the EU's competences in the areas of 'internal market' and 'agriculture and fisheries', form so called 'shared competences' between the EU and its Member States (Art. 4(2)(a), (d) TFEU).

[92] Art. 26(2), 34 et seq. TFEU.

German Law

Like the ChFR the German constitution, *i.e.* the Basic Law, provides for fundamental rights which call for State action ensuring food security.[93] This holds true for the rights to "life" and "physical integrity"[94] and the right to "property".[95] As far as farmers are concerned they enjoy the right to choose and to pursue an occupation.[96] In addition, the right to human dignity[97] in connection with the "social state" principle[98] imposes on the government the duty to guarantee each individual a subsistence minimum.[99] According to the Federal Constitutional Court, each person in need of assistance is entitled to all the "material prerequisites which are indispensable for his or her physical existence".[100]

As Germany is a federal State, the legislative and administrative competences are split between the Federation and the German States, *i.e.* the 'Länder'.[101] Accordingly, the competence to legislate on matters of food security lies (explicitly)[102] with the 'Länder' unless the federal legislature exercises its legislative power by adopting a law.[103] Moreover, the federal legislator has the competence in the area of "the promotion of agricultural production and forestry … , … the importation and exportation of agricultural and forestry products, deep-sea and coastal fishing"[104] as well as in the area of "the law on food products including animals used in their production, the law on … feedstuffs as well as protective measures in connection with the marketing of agricultural and forest seeds and seedlings, the protection of plants against diseases and pests, as well as the protection of animals".[105]

In general, the federal laws adopted on the basis of these competences are executed by the 'Länder'.[106] By way of exception, the federal government may establish federal agencies implementing and enforcing federal laws. On this constitutional basis,[107] the BVL has been established.

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[93] Concerning the duty to protect arising from fundamental rights under the German constitution see BVerfGE 39, 1, at 41.

[94] Art. 2(2)(1) GG.

[95] Art. 14(1)(1) GG.

[96] Art. 12(1) GG.

[97] Art. 1(1) GG.

[98] Art. 20(1), 28(1)(1) GG.

[99] BVerfGE 125, 175, at 222 = BVerfG, Judgment of 9 February 2010, 1 BvL 1, 3 and 4/09, para. 133 (http://www.bverfg.de/entscheidungen/ls20100209_1bvl000109en.html).

[100] BVerfGE 125, 175, at LS 1 = BVerfG, Judgment of 9 February 2010, 1 BvL 1, 3 and 4/09, headnote 1 (http://www.bverfg.de/entscheidungen/ls20100209_1bvl000109en.html).

[101] See Art. 30, 70 et seq., 83 et seq. GG.

[102] "[E]nsuring the adequacy of food supply".

[103] Art. 72(1), 74(1)(17) GG.

[104] Art. 74(1)(17) GG.

[105] Art. 74(1)(20) GG.

[106] Art. 83, 84 GG.

[107] Art. 87(1)(1) GG.

Legal Superstructure of Genetic Engineering Law

Public International Law

Both the EU and Germany are parties to the Convention on Biological Diversity (CBD)[108] and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CP).[109] They have also signed, and recently also ratified, the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (NKP).[110]

According to the CBD, States parties are required to adopt rules for the purpose of the safe handling of living modified organisms (LMOs) resulting from modern biotechnology,[111] *i.e.*, especially, of GMOs. The CP provides for detailed rules to be followed by States with regard to the transboundary movement of LMOs. The rules applicable in case of damage caused by the transboundary movement of LMOs are laid down in the NKP.

Besides international treaty law on biodiversity other environmental treaties might be applicable with regard to GMOs as well. In addition, as far as it concerns the State's obligation to protect the individual from risks to life, health or property, international human rights instruments both on the universal and on the regional level come into play.[112] In this context it is noteworthy that the European Court of Human Rights (ECtHR) has construed the right to respect for private and family life[113] as to impose the duty on the State to protect individuals from adverse environmental effects.[114]

In addition, WTO law may come into play as well. In particular, the GATT[115] as well as the SPS Agreement[116] and the TBT Agreement[117] may be applicable and impose obstacles on the regulation of genetic engineering. *E.g.*, the Panel in the *Biotech Products* case considered the *de facto*-moratorium adopted by the EU and

[108] OJ L 309, 13.12.1993, p. 3; BGBl. 1993 II p. 1742.

[109] OJ L 201, 31.7.2002, p. 48; BGBl. 2003 II S. 1506.

[110] OJ L 46, 19.2.2013, p. 4; BGBl. 2013 II p. 618.

[111] Cf. Art. 8(g), 19(3), (4) CBD.

[112] Concerning the right to life see Art. 6 (1)(1) ICCPR, Art. 2(1)(1) ECHR; concerning the right to health see Art. 12(1) ICESCR; concerning the right to property see Art. 1(1)(1) of the (first) Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms, Art. 15(2), 16(1)(h) CEDAW, Art. 5(d)(v) of the International Convention on the Elimination of All Forms of Racial Discrimination (CERD; BGBl. 1969 II p. 961).

[113] Art. 8(1) ECHR.

[114] For a more detailed analysis see, e.g., Julia Iliopoulos-Strangas, Soziale Grundrechte, in: Dieter Merten/Hans-Jürgen Papier (eds.), Handbuch der Grundrechte, Vol. VI/1, 2010, § 145, para. 62 et seq.; Roman Schmidt-Radefeldt, Ökologische Menschenrechte, 2000, p. 66 et seq.

[115] General Agreement on Tariffs and Trade (GATT 1947: BGBl. 1952 II p. 173; GATT 1994: OJ L 336, 23.12.1994, p. 11).

[116] Agreement on the Application of Sanitary and Phytosanitary Measures (OJ L 336, 23.12.1994, p. 40).

[117] Agreement on Technical Barriers to Trade (OJ L 336, 23.12.1994, p. 86).

halting the marketing approval of GM products[118] an infringement of the SPS Agreement.[119]

Concerning the legal superstructure of genetic engineering law on the international level, treaty law is complemented by customary law. In this respect, the most fundamental customary law rule is that States have "to ensure that activities within their jurisdiction or control respect the environment of other States or of areas beyond national control".[120] This rule "is now part of the corpus of international law relating to the environment".[121] It is closely related to the 'principle of prevention' or the 'duty of prevention' respectively which "has now become a principle of general international law"[122] and according to which States "shall take all appropriate measures to prevent significant transboundary harm or at any event to minimize the risk thereof".[123] More specifically, "it may now be considered a requirement under general international law to undertake an environmental impact assessment where there is a risk that the proposed … activity may have a significant adverse impact in a transboundary context".[124]

In addition, several 'soft law' principles of international environmental law provide for norms which are not legally binding but constitute widely, if not universally, recognized standards of 'good environmental practice' of States. Specifically with regard to GMOs, this holds true, *e.g.*, for the principle of sustainable development,[125] the precautionary principle,[126] the polluter-pays-principle[127] and the

[118] See also infra at section "Restriction of GMO" (in and at fn. 195–197).

[119] WTO Panel Report European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 8.13 et seq.

[120] ICJ, Legality of the Threat or Use of Nuclear Weapons, ICJ Reports 1996, p. 226, para. 29.

[121] ICJ, Legality of the Threat or Use of Nuclear Weapons, ICJ Reports 1996, p. 226, para. 29.

[122] PCA-Arbitration Regarding the Iron Rhine ("Ijzeren Rijn") Railway between the Kingdom of Belgium and the Kingdom of the Netherlands, Award of the Arbitral Tribunal, 24 May 2005, para. 59; see also ICJ, Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment, ICJ Reports 2010, p. 14, para. 101: "the principle of prevention, as a customary rule".

[123] Art. 3 ILC Draft Articles on Prevention of Transboundary Harm from Hazardous Activities 2001, in: Official Records of the General Assembly, Fifty-sixth Session, Supplement No. 10 (A/56/10).

[124] ICJ, Case concerning pulp mills on the River Uruguay (Argentina v. Uruguay), ICJ Reports 2010, p. 14, para. 204.

[125] According to which a "balance between economic development and environmental protection" has to be struck what "is the essence of sustainable development" (ICJ, Case concerning pulp mills on the River Uruguay [Argentina v. Uruguay], ICJ Reports 2010, p. 14, para. 177).

[126] According to which "lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (Principle 15 of the Rio Declaration on Environment and Development of 1992).

[127] According to which "the polluter should, in principle, bear the cost of pollution" (Principle 16 of the Rio Declaration on Environment and Development of 1992).

'source principle'[128] as well as the concepts of common concern of humankind[129] and common heritage of humankind.[130]

European Union Law

The legal superstructure of genetic technology law is also composed of EU law. Concerning the EU's and its Member States' duty to protect individuals from environmental and health risks associated with the use of GMOs the ChFR[131] has to be taken into account, in particular its provisions on the "right to life",[132] "right to respect for his or her physical …integrity",[133] the "freedom to conduct a business",[134] and the "right to property".[135] In addition, both a "high level of human health protection"[136] and a "high level of environmental protection"[137] as well as a "high level of consumer protection"[138] shall be ensured. According to its competences, the EU also holds the power to legislate on the contained use of GMOs,[139] on the release into the environment and placing on the market of GM food[140] and on consumer protection.[141]

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[128] According to which "environmental damage should as a priority be rectified at source" (Art. 191(2)(2) TFEU).

[129] According to which the international community has a common interest in the conservation of, inter alia, biological diversity (see para. 3 of the CBD preamble). Concerning the 'common concern' concept see, e.g., Alexandre Kiss/Dinah Shelton, Guide to International Environmental Law, 2007, p. 13 et seq.

[130] According to which the environment of areas beyond national jurisdiction (e.g., high seas, deep sea bed, Antarctica) must not be adversely affected in the course of activities carried out in the area concerned. See also Rüdiger Wolfrum, Common heritage of mankind, in: Rüdiger Wolfrum (ed.), The Max Planck Encyclopedia of Public International Law, 2009, online edition (www.mpepil.com).

[131] Concerning its scope of application see supra in and at fn. 88–89.

[132] Art. 2(1) ChFR.

[133] Art. 3(1) ChFR.

[134] Art. 16 ChFR.

[135] Art. 17 ChFR.

[136] Art. 35(2) ChFR.

[137] Art. 37 ChFR.

[138] Art. 38 ChFR.

[139] Art. 192(2) TFEU.

[140] Art. 114(1)(2) TFEU.

[141] Art. 169(2) TFEU.

German Law

On the domestic level, the legal superstructure of genetic technology law is framed by fundamental rights, in particular by the right to life and physical integrity,[142] the freedom of science and research,[143] the right to property,[144] and the right to choose and practice an occupation.[145] In addition, the State has to comply with its duty to protect the environment.[146] Moreover, the 'social state' principle[147] might arguably call for consumer protection by the State.

The legislative powers in the entire area of genetic engineering lie with the 'Länder' so long as and to the extent that the Federation has not exercised its legislative powers.[148] At present, all uses of GMOs are covered by the federal law on genetic engineering, *i.e.* the GenTG. Hence, the federal legislator has exhausted the competence in the field of genetic engineering. Therefore, the 'Länder' are barred from adopting additional, *e.g.*, more prohibitive, rules on the use of GMOs. The situation would change if the federal legislature returned parts of the legislative competences in the area of genetic engineering to the 'Länder', *e.g.*, as far as restrictions on, or prohibitions of, the cultivation of GM crops is concerned.

The federal rules on genetic engineering, *i.e.* the GenTG and its accompanying statutory instruments, have to be implemented and enforced by the 'Länder'.[149] However, by way of exception, the Federation may establish federal agencies for the purpose of executing its laws. In fact, in the field of genetic engineering, the Federation has made use of this administrative competence by establishing the BVL and transferring the power to implement and enforce the federal rules on the deliberate release of GMOs into the environment and the placing on the market of GMOs upon the BVL.[150]

[142] Art. 2(2)(1) GG.

[143] Art. 5(3)(1) GG.

[144] Art. 14(1)(1) GG.

[145] Art. 12(1) GG.

[146] Art. 20a GG.

[147] Art. 20(1), 28(1)(1) GG.

[148] Art. 72(1), 74(1)(26) GG and BVerfGE 128, 1, at LS 1 = BVerfG, Judgment of 24 November 2010, 2 BvF 2/05, headnote 1 (http://www.bverfg.de/entscheidungen/fs20101124_1bvf000205en.html).

[149] Art. 30, 83, 84(1)(1) GG.

[150] Cf. Art. 87(3)(1) GG and Sec. 31 GenTG.

General Aspects

Due to the doctrine of supremacy of EU law[151] and constitutional law,[152] domestic law which is applicable to genetic engineering and food security must be in conformity with both EU law and German constitutional law. From the German dualist[153] perspective, on the other hand, public international law does not prevail over conflicting domestic law. However, the lawmakers have to reconcile domestic law with Germany's obligations under public international law[154] unless the fulfilment of such public international law obligations runs counter our fundamental constitutional principles.[155] From a constitutional point of view, also the doctrine of supremacy of EU law is limited by Germany's constitutional identity[156] as well as the *ultra vires* doctrine according to which EU law must be disregarded if it has been adopted beyond the EU's competences.[157] In addition, domestic law has to be interpreted and applied in the light of constitutional law,[158] EU law[159] and public international law.[160]

Outline of the Relevant Law

From a German perspective, both fields of law, *i.e.* genetic engineering law and food law, are clearly dominated by EU law.[161] Thus, EU law provides for the decisive legal rules which govern GMOs as well as food both on the EU level and on the domestic level.

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[151] ECJ, Case 6/64, Costa ./. E.N.E.L., ECR 1964, p. 1253, at 1269 et seq.

[152] Art. 1(3), 20(3) GG.

[153] See BVerfGE 111, 307, at 318 = = BVerfG, Order of 14 October 2004, 2 BvR 1481/04, para. 34 (http://www.bverfg.de/entscheidungen/rs20041014_2bvr148104en.html).

[154] See also BVerfGE 112, 1, at 26 = BVerfG, Order of 26 October 2004, 2 BvR 955/00, 1038/01, para. 93 (http://www.bverfg.de/entscheidungen/rs20041026_2bvr095500en.html).

[155] See BVerfGE 111, 307, at 319 = BVerfG, Order of 14 October 2004, 2 BvR 1481/04, para. 35–36 (http://www.bverfg.de/entscheidungen/rs20041014_2bvr148104en.html).

[156] BVerfGE 123, 267, at 354 = BVerfG, Judgment of 30 June 2009, 2 BvE 2 and 5/08, 2 BvR 1010, 1022 and 1259/08, 182/09, para. 240 (http://www.bverfgde/entscheidungen/es20090630_2bve000208en.html).

[157] According to the Federal Constitutional Court, the breach of competences on the part of the EU must be "sufficiently qualified", i.e. "manifestly" and "leading to a structurally significant shift to the detriment of the Member States in the structure of competences" (BVerfGE 126, 286, at LS 1a = BVerfG, 2 BvR 2662/06 of 6 July 2010, headnote 1a, http://www.bverfg.de/entscheidungen/rs20100706_2bvr266106en.html).

[158] BVerfGE 7, 198, at 208.

[159] ECJ, Case 14/83, Von Colson and Kamann, ECR 1984, p. 1891, para. 26, 28.

[160] BVerfGE 74, 358, at 370.

[161] Cf. also Rudolf Streinz, Rechtliche Aspekte, in: Dieter Sturma/Dirk Lanzerath/Bert Heinrichs (eds.), Gentechnik in der Lebensmittelproduktion, 2011, p. 58.

General Genetic Engineering Law

The general legal framework for genetic engineering, *i.e.* for the creation and any uses of GMOs, is composed of Directive 2009/41/EC,[162] Directive 2001/18/EC,[163] Regulation (EC) No. 1830/2003,[164] and Regulation (EC) No. 1946/2003.[165] The latter EU regulation implements the Cartagena Protocol.[166] These directives and regulations are complemented by numerous regulations and decisions as well as (non-binding)[167] recommendations.[168]

EU regulations are "binding in [their] entirety and directly applicable in all the Member States",[169] whereas EU Directives are, in general,[170] not directly applicable but have to be implemented by the Member States.[171] Accordingly, the Directives 2009/41/EC and 2001/18/EC have been implemented into the German legal order by the GenTG and additional statutory instruments based on the GenTG.[172] In addition to these federal rules, the 'Länder', *i.e.* the 16 German States constituting the Federal Republic of Germany,[173] have adopted laws, statutory instruments or administrative instructions on which administrative entities are responsible for the execution of the federal rules in the field of contained use of GMOs.[174] Although EU regulations are directly applicable, their execution on the national level may necessitate further domestic legal rules. In Germany, the EC Genetic Engineering

[162] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).

[163] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

[164] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

[165] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

[166] Concerning the Cartagena Protocol see supra at section "Legal superstructure" (in and at fn. 111).

[167] Art. 288(5) TFEU.

[168] See Matthias Herdegen/Hans-Georg Dederer, Internationales Biotechnologierecht, EU-Recht/Regelungen, 2. Richtlinie 2001/18/EG, fn. 1, 4. Verordnung (EG) Nr. 258/97, fn. 1, 5. Verordnung (EG) Nr. 1829/2003, fn. 1, 7. Verordnung (EG) Nr. 1830/2003, fn. 1.

[169] Art. 288(2) TFEU.

[170] For exceptions see ECJ, Case 41/74, Van Duyn, ECR 1974, p. 1337, para. 12.

[171] Cf. Art. 288(3) TFEU.

[172] For a full list see Wolfram Eberbach/Peter Lange/Michael Ronellenfitsch, Recht der Gentechnik und Biomedizin (GenTR/BioMedR), Teil I, C.

[173] See preamble cl. 2 GG.

[174] For a full list see Wolfram Eberbach/Peter Lange/Michael Ronellenfitsch, Recht der Gentechnik und Biomedizin (GenTR/BioMedR), Teil I, E.

Implementation Law (EG-Gentechnik-Durchführungsgesetz – EGGenTDurchfG)[175] lays down detailed provisions on which national authority is competent for, and involved in, the execution of Regulations (EC) No. 1829/2003, 1830/2003 and 1946/2003. As far as the cultivation of GM food crops is concerned, the Federal Nature Conservation Law (Bundesnaturschutzgesetz – BNatSchG)[176] may have to be adhered to as well.[177]

General Food Law

As far as general food law is of interest in the present context, the general legal framework for food is made up of Regulation (EC) No. 178/2002,[178] Regulation (EC) No. 834/2007[179] and Directive 2000/13/EC.[180] On the domestic level, the LFGB and the Statutory Instrument on Food Labelling (Lebensmittel-Kennzeichnungsverordnung – LMKV)[181] have to be taken into account as well.

[175] Gesetz zur Durchführung der Verordnungen der Europäischen Gemeinschaft oder der Europäischen Union auf dem Gebiet der Gentechnik und über die Kennzeichnung ohne Anwendung gentechnischer Verfahren hergestellter Lebensmittel (BGBl. 2004 I p. 1244), last amended by law of 9 December 2010 (BGBl. 2010 I p. 1934).

[176] Gesetz über Naturschutz und Landschaftspflege (BGBl. 2009 I p. 2542), last amended by law of 7 August 2013 (BGBl. 2013 I p. 3154).

[177] See Sec. 34, 35 BNatSchG. Sec. 34 BNatSchG implements Art. 6 of the Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ L 206, 22.7.1992, p. 7.

[178] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

[179] Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No. 2092/91 (OJ L 189, 20.7.2007, p. 1).

[180] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). This Directive will expire on 13 December 2014 and substituted by Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004 (OJ L 304, 22.11.2011, p. 18).

[181] Verordnung über die Kennzeichnung von Lebensmitteln (BGBl. 1999 I p. 2464), last amended by law of 25 July 2013 (BGBl. 2013 I p. 2722).

GM Food Law

When it comes to GM food, *i.e.* GMOs for food use, food containing or consisting of GMOs, or food produced from or containing ingredients produced from GMOs (hereinafter: GM food),[182] it is again EU law which provides for the relevant rules being directly applicable throughout the whole Union. These rules are laid down in Regulation (EC) No. 1829/2003.[183] This regulation might be looked upon as being anchored somehow in between general genetic engineering law and general food law. It refers, *e.g.*, with regard to legal definitions,[184] risk assessment[185] or safeguard measures,[186] to general genetic engineering law as well as to general food law. From this standpoint, the regulatory framework for GM food seems to rest on two pillars: genetic engineering law and food law. Nevertheless, from a systematic point of view, GM food law, *i.e.* Regulation (EC) No. 1829/2003, has to be regarded as being part of genetic engineering law. Its essential features (*e.g.*, prior marketing approval based on an assessment of risks to health and the environment due to the use of genetic modification techniques) are typical for the EU's regulatory approach to GMOs and untypical for the EU's regulatory approach to food. This holds true all the more as both Regulation (EC) No. 1830/2003 and Regulation (EC) No. 1946/2003, which belong to the general legal framework for GMOs, also refer to particular regulatory aspects of GM food.[187] With regard to those aspects of GM food which are not GM specific general food law is, of course, applicable additionally.

Objectives

The overall purpose of the EU legal framework for GM food is to "ensur[e] a high level of protection of human life and health, … environment and consumer interests …, whilst ensuring the effective functioning of the internal market".[188] In order to

[182] See Art. 3(1) Regulation (EC) No. 1829/2003.

[183] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

[184] See, e.g., Art. 2(1) Regulation (EC) No. 1829/2003 referring to general food law for the purpose of the definitions of 'food' and 'feed'; Art. 2(5) referring to general genetic engineering law for the purpose of the definition of 'GMO'.

[185] See, e.g., Art. 5(5)(a) Regulation 1829/2003 referring to general genetic engineering law.

[186] See Art. 34 Regulation (EC) No. 1829/2003 referring to general food law.

[187] See, e.g., Art. 5 Regulation (EC) No. 1830/2003; Art. 9–10 Regulation (EC) No. 1946/2003.

[188] Art. 1(a) Regulation (EC) No. 1829/2003. Concerning the change of the EU legislator's regulatory philosophy which was to ensure environmental and health protection at the beginning in 1990 but which has been extended to include consumer interest protection as well in 2001/2003 (particularly with regard to ensuring that consumers can make an informed choice), see Hans-Georg Dederer, Neues von der Gentechnik, Zeitschrift für das gesamte Lebensmittelrecht 2005, p. 307, at 308–310; Gernot Schubert, Paradigmenwechsel im Gentechnikrecht?, GenTechnik & Recht 2003, p. 47, at 53.

achieve these objectives EU law provides for a rigorous pre-marketing safety assessment of GM food, transparent labelling requirements enabling consumers to make an informed choice, and strict post-marketing measures which include thorough monitoring and continuous traceability of GM food. It is especially Regulation (EC) No. 1829/2003 which regulates the market authorisation and supervision of GM food as well as GM specific labelling of GM food. Its norms are complemented by Regulation (EC) No. 1830/2003 which provides a framework for the traceability of GM food "with the objectives of facilitating accurate labelling, monitoring the effects on the environment and … on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products".[189] In case of export of GM food to third countries Regulation (EC) No. 1946/2003 has to be adhered to. It implements the Cartagena Protocol for all EU Member States and establishes "a common system of notification and information for transboundary movements of … GMOs"[190] intended for direct use as food or for food processing.[191]

Scope

Regulation (EC) No. 1829/2003 only applies to GM food, *i.e.* to GMOs for food use, food containing or consisting of GMOs, and food produced from GMOs or containing ingredients produced from GMOs. Thus, it does not apply to food produced 'with' GMOs.[192]

Authorisation

GM food must not be marketed unless on the basis, and in accordance with, a valid marketing authorisation issued, in general,[193] by the European Commission. The rules concerning the authorisation requirements and procedure are laid down in Regulation (EC) No. 1829/2003. This authorisation may also cover the cultivation of the respective GMO. According to Regulation (EC) No. 1946/2003, prior authorisation is also required for GMOs intended for direct use as food or for processing and to be exported to third States unless the country of destination has expressly agreed to the import.[194]

[189] Art. 1 Regulation (EC) No. 1830/2003.

[190] Art. 1 Regulation (EC) No. 1946/2003.

[191] See Art. 9–10 Regulation (EC) No. 1946/2003.

[192] In detail infra at section "Admission of GMO in food production" (in and at fn. 251–256).

[193] For rare exceptions see infra at section "Admission of GMO in food production" (in and at fn. 337).

[194] See Art. 10(3)(2) Regulation (EC) No. 1946/2003.

Risk Assessment

The authorisation must be based on a risk assessment carried out by the European Food Safety Authority (EFSA) in accordance with Regulation (EC) No. 1829/2003 and Directive 2001/18/EC.

Labelling

GM food has to be labeled as such, *i.e.* it is subject to GM specific labelling requirements according to which the label must expressly state, *e.g.*, that the food is "genetically modified" or has been "produced from genetically modified [name of organism]". These labelling provisions are laid down in Regulation (EC) No. 1829/2003 according to which the GM specific labelling requirements are, however, inapplicable if the presence of GM material is both below a certain minimum threshold and if such traces of GMOs are adventitious or technically unavoidable. In addition, the general labelling rules as provided for in Directive 2000/13/EC have to be complied with. Moreover, concerning the labelling of food produced without use of genetic engineering techniques, it is domestic law, *i.e.* the EGGenTDurchfG, which contains the pertinent rules.

Traceability

GM food is subject to certain traceability requirements. Within the production and distribution chain each operator has to transmit and hold specified information relating to the GMO and its presence. The relevant rules are provided in Regulation (EC) No. 1830/2003. The traceability requirements are not applicable if the presence of GM material is adventitious or technically unavoidable and does not exceed a minimum threshold.

Monitoring

The authorisation granted in accordance with Regulation (EC) No. 1829/2003 may require post-market monitoring. The monitoring shall, where appropriate, relate to the use of the GM food. If GMOs as such or food containing or consisting GMOs are concerned, the monitoring of environmental effects is compulsory.

Prior Research and Development

Directive 2009/41/EC on the contained use of genetically modified micro-organisms (GMMs) may apply in the phase of GM food research and development. As far as subsequent field trials with GM plants are concerned, the pertinent rules governing the release of GMOs into the environment are set out in Directive 2001/18/EC and in the GenTG which implements the said directive.

Admission

Restriction of GMO

Moratoria

Currently, moratoria exist neither on the EU level nor on the domestic level. The *de facto*-moratorium for market authorisations of GMOs which was adopted by the ministers for the environment of the EU Member States in 1999[195] ended in 2003[196] or 2004[197] respectively.

Invocation of Safeguard Clauses

EU law and, accordingly, domestic law provide for safeguard clauses. With regard to GM food safeguard measures may be based on Regulation (EC) No. 1829/2003 in connection with Regulation (EC) No. 178/2002[198] or – as far as it concerns the cultivation of GM food crops – on Directive 2001/18/EC[199] in connection with implementing domestic legislation.[200]

Emergency measures under Regulation (EC) No. 1829/2003 are triggered by findings which reveal that a GM food is likely to constitute a serious risk to human health or the environment or by an opinion of the EFSA which provokes the need to suspend or modify urgently the GM food's authorisation.[201] Concerning the procedures to be followed in such emergency cases, Art. 34 Regulation (EC) No. 1829/2003 refers to Art. 53, 54 Regulation (EC) No. 178/2002. According to these norms, it is primarily the European Commission which has to adopt the necessary

[195] For further information see Matthias Herdegen/Hans-Georg Dederer, in: Internationales Biotechnologierecht, EU-Recht/Erläuterungen, 2. Richtlinie 2001/18/EG, para. 1 (2010).

[196] When the Regulations (EC) No. 1829/2003, 1830/2003 and 1946/2003 were passed forming henceforward the revised legal framework for a stricter regulation of GMOs (together with Directive 2001/18/EC adopted earlier in 2001).

[197] When the Regulations (EC) No. 1829/2003, 1830/2003 and 1946/2003 became applicable (on 18 April 2004) or when the first GM product approval was issued again (on 19 May 2004; see Commission Decision 2004/657/EC of 19 May 2004 authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council [OJ L 300, 25.9.2004, p. 48]) respectively.

[198] See Art. 34 Regulation (EC) No. 1829/2003; Art. 53, 54 Regulation (EC) No. 178/2002.

[199] See Art. 23 Directive 2001/18/EC.

[200] See Sec. 20(2) GenTG.

[201] See Art. 34 Regulation (EC) No. 1829/2003.

emergency measures, *e.g.*, the suspension of the sale of the GM food concerned.[202] The Member States may adopt interim protective measures, though, as long as the Commission has not taken action.[203]

Directive 2001/18/EC provides that Member States may provisionally restrict or prohibit the use or sale of a GM product, *e.g.*, of a GM crop plant, if "detailed grounds" support the conclusion that the GM product constitutes a risk to human health or the environment. These "detailed grounds" must be based on new or additional information or on new or additional scientific knowledge provoking the reassessment of existing information.[204] It is, in general, the European Commission which will take the final decision on the respective Member State's safeguard measure in accordance with the so called 'comitology procedure'.[205] These provisions have been implemented into German law.[206]

On April 17, 2009, Germany invoked the safeguard clauses of Directive 2001/18/EC[207] and the GenTG[208] as well the safeguard clause of Regulation (EC) No. 1829/2003[209] with regard to MON810.[210] The safeguard measure ordered the temporary suspension of the French market authorisation for MON810 (Bt maize) as far as it concerns the cultivation of seeds of the GM variety MON810. This safeguard measure has been upheld by the administrative courts.[211] On the other hand, the ZKBS has brusquely criticized the safeguard measure as being scientifically unfounded. Hence, a WTO Panel might well consider the safeguard measure a violation of the SPS Agreement.[212]

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[202] See, e.g., Art. 53(1)(a)(i) Regulation (EC) No. 178/2002.

[203] See Art. 54(1)(1) Regulation (EC) No. 178/2002.

[204] Art. 23(1)(1) Directive 2001/18/EC.

[205] See Art. 23(2), 30(2) Directive 2001/18/EC.

[206] See Sec. 20(2), 26(5)(2)-(3) GenTG.

[207] Art. 23 Directive 2001/18/EC.

[208] Sec. 20(2) GenTG.

[209] Art. 34 Regulation (EC) No. 1829/2003.

[210] http://www.bvl.bund.de/SharedDocs/Downloads/08_PresseInfothek/mon_810_bescheid.pdf?__blob=publicationFile

[211] Verwaltungsgericht Braunschweig, Order of 4 May 2009, 2 B 111/09, Gewerbearchiv 2009, p. 412; Oberverwaltungsgericht Lüneburg, Order of 28 May 2009, 13 ME 76/09, Natur und Recht 2009, p. 566. Finally, the claimant withdrew its action (see Verwaltungsgericht Braunschweig, Order of 11 February 2010, 2 A 110/09). As a result, there will be no decision on the merits.

[212] Cf. WTO Panel Report European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R, p. 1037 et seq. See also Hans-Georg Dederer, Die Nutzung der Gentechnik, in: Reinhard Hendler/Peter Marburger/Peter Reiff/Meinhard Schröder (eds.), Landwirtschaft und Umweltschutz, 2007 (UTR vol. 92), p. 185.

Subsidies for a GMO-Free Production

In Germany, subsidies for the purpose of stimulating specifically GMO-free production do not exist. However, the 'Länder', *i.e.* the federal States, award subsidies for organic production.[213] Such subsidies indirectly offer an incentive to start or intensify GMO-free production because Regulation (EC) No. 834/2007 provides that "[t]he use of GMOs in organic production is prohibited".[214]

'GMO-Free Zones'

Neither EU law nor domestic law provides for legal rules governing the establishment of GMO-free zones explicitly. However, coexistence or natural conservation measures may result in GMO-free zones.[215]

As far as it concerns coexistence of GM, conventional and organic crop production, the European Commission has adopted a recommendation[216] on the basis of Directive 2001/18/EC.[217] This recommendation is not legally binding, though.[218] According to this recommendation, "under certain economic and natural conditions, Member States should consider the possibility to exclude GMO cultivation from large areas of their territory to avoid the unintended presence of GMOs in conventional and organic crops".[219] The establishment of a GMO-free zone as a measure of coexistence may, however, apply to specific GMOs only but not to all GMOs in general. For the purpose of coexistence measures is to avoid the unintended presence of GMOs in conventional or organic crops.[220] The presence of GMOs in other types of crops depends on whether and to what extent GMOs are capable of admixing with such other crops. As far as it concerns cultivation, the capability of such admixture depends on whether GM material may be passed on, *e.g.*, by pollination, from GM plants to neighbouring crop. Thus, *e.g.*, GM material from GM maize cannot 'contaminate' conventional or organic rapeseed because maize and rapeseed are not able to crossbreed.

So far, German law does not explicitly provide for coexistence measures taking the form of GMO-free zones. Rather, the GenTG provides that GM farmers have to take precautionary measures in order to ensure that the principle of coexistence is

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[213] See, e.g., with regard to Bavaria https://www.stmelf.bayern.de/agrarpolitik/foerderung/001007/

[214] Recital 30, Art. 4(a)(iii), Art. 9 Regulation (EC) No. 834/2007.

[215] For an in-depth analysis see Hans-Georg Dederer, Weiterentwicklung des Gentechnikrechts – GVO-freie Zonen und sozioökonomische Kriterien der GVO-Zulassung, 2010, p. 12 et seq.

[216] Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops (OJ C 200, 22.7.2010, p. 1).

[217] Art. 26a(2) Directive 2001/18/EC.

[218] See Art. 288(5) TFEU.

[219] Para. 2.4 Commission Recommendation No. 2010/C 200/01.

[220] Cf. Art. 26a(1) Directive 2001/18/EC.

not significantly impaired by the admixture of GMOs with other crops.[221] This obligation is fulfilled by adhering to standards of good professional practice.[222] With regard to GM crops, these good practice standards are laid down in a statutory instrument.[223] An annex to this regulation provides for precise coexistence measures with regard to GM maize. According to this annex, *e.g.*, GM farmers have to respect isolation distances between their field and neighbouring fields of conventional or organic farmers. These isolation distances amount to 150 m vis-à-vis conventional crops and 300 m vis-à-vis organic crops. Depending on the shape, size and dispersal of fields in a given region, GM farmers may not be able to abide by these isolation distances. Thus, in such a case, the respective region becomes *de facto* a GMO-free zone with regard to those GM crops to which the unrealisable isolation distances apply.

With regard to seed production, the Seed Commerce Law (Saatgutverkehrsgesetz – SaatG)[224] provides that the 'Länder' may set up so called 'closed production areas'.[225] Accordingly, *e.g.*, Baden-Württemberg passed a Law for the Protection of Seed Production in Closed Production Areas[226] which provides for the establishment of closed production areas through statutory instruments.[227] Such statutory instruments may define closed areas for the production of conventional or organic seed[228] and, as a consequence, prohibit the cultivation of cross breeding GM crops.[229]

As far as it concerns natural conservation, GMOs may pose risks to fauna and flora or to ecosystems. Therefore, *e.g.*, already the market authorisation may include "conditions for the protection of particular ecosystems/environment and/or geographical areas".[230] Such areas ('zones') must be 'GMO-free' with regard to the authorized GMO only. Safeguard measures may also take the form of a prohibition to cultivate a certain GMO in a particular region. Similarly, in accordance with the BNatSchG, the cultivation of a GMO may be subject to an assessment of its impacts on a Natura 2000-site. If, according to this assessment, the cultivation of the respective GMO is likely to have significant adverse effects on those components which

[221] Sec. 16b(1)(1) GenTG.

[222] Sec. 16b(2) GenTG.

[223] Verordnung über die gute fachliche Praxis bei der Erzeugung gentechnisch veränderter Pflanzen (Gentechnik-Pflanzenerzeugungsverordnung – GenTPflEV). In detail see Hans-Georg Dederer, Gentechnikrecht, in: Ines Härtel (ed.), Handbuch des Fachanwalts Agrarrecht, 2012, Kapitel 20, para 25 et seq.

[224] BGBl. 2004 I p. 1673, last amended by law of law of 7 August 2013, BGBl. 2013 I 3154.

[225] Sec. 29 SaatG.

[226] Gesetz zum Schutz der Erzeugung von Saatgut in geschlossenen Anbaugebieten (SaatErzG), GBl. 1969 p. 80.

[227] Sec. 1(1) SaatErzG.

[228] Cf. Sec. 1(2) SaatErzG.

[229] Cf. Sec. 2(1)(1) SaatErzG.

[230] Art. 7(2) in connection with Art. 6(5)(e) Regulation (EC) No. 1829/2003. A similar provision is laid down in Art. 19(3)(c) Directive 2001/18/EC in connection with Sec. 16d(1)(3) GenTG.

are decisive for the site's conservation objectives, the cultivation of the GMO is prohibited and must be banned.[231]

In addition, on the local level, district and county councils have adopted resolutions calling for GMO-free agricultural production within their territory.[232] Such resolutions are not legally binding on farmers. What is more, it is even disputable whether these resolutions are lawful because the municipalities or counties respectively might have acted *ultra vires*, *i.e.* beyond the limits of their competences which are restricted to matters of the local community.[233] It is likewise questionable whether a municipality may oblige farmers cultivating the municipality's real property to adhere to a clause laid down in their tenancy agreement providing for the use of GMO-free production methods.[234]

Of course, conventional and organic farmers may enter into agreements in which they commit themselves to GMO-free agriculture. Such private contracts could result in GMO-free zones which, in turn, would not be attributable to the EU Member State concerned.[235]

The question of whether zones being completely free of any GMOs could be lawfully established directly on the basis of the TFEU has to be answered in the negative as a rule. The TFEU[236] provides for a derogation clause according to which EU Member States may unilaterally introduce national provisions deviating from harmonisation measures adopted by the EU legislator. Such domestic derogations from Regulation (EC) No. 1829/2003 and Directive 2001/18/EC can hardly form the legal basis for a comprehensive ban of GMO cultivation in a Member State's territory or parts of it, though. The Member States bear the full burden of proof that such prohibitions covering all kinds of GM crops are "based on new scientific evidence relating to the protection of the environment … on grounds of a problem

[231] Sec. 35(2) in connection with Sec. 34(1), (2) BNatSchG; similarly Art. 21(2) of the Bavarian Nature Conservation Law (Gesetz über den Schutz der Natur, die Pflege der Landschaft und die Erholung in der freien Natur [Bayerisches Naturschutzgesetz – BayNatSchG], GVBl. 2011 p. 82; last amended by law of 8 April 2013, GVBl. 2013 p. 174). In detail see, e.g., Hans-Georg Dederer, Gentechnikrecht, in: Ines Härtel (ed.), Handbuch des Fachanwalts Agrarrecht, 2012, Kapitel 20, para 91 et seq.; Christoph Palme/Jochen Schumacher, Die Regelungen zur FFH-Verträglichkeitsprüfung bei Freisetzung oder Inverkehrbringen von gentechnisch veränderten Organismen in § 34a BNatSchG, Natur und Recht 2007, p. 16.

[232] In Bavaria, more than 200 municipalities and counties have admitted to GMO-free agriculture on their territories. See http://www.stmuv.bayern.de/umwelt/gentechnik/index.htm

[233] Cf. Art. 28(2) GG. See Michael Greiner, Befassungskompetenz kommunaler Gremien mit Fragen der Gentechnik („Gentechnikfreie Zone"), KommunalPraxis BY 2004, p. 376.

[234] See Hans-Dieter Laser, Ausbringen von genetisch veränderten Organismen und Pflanzen auf gemeindeeigenen Grundstücken, KommunalPraxis BY 2005, p. 384.

[235] Only under very exceptional circumstances one could imagine that a Member State is obliged to intervene, e.g., by nullifying such private agreements, for the purpose of guaranteeing the free circulation of authorized GMOs on the basis of Art. 22 Directive 2001/18/EC (cf. also Art. 7(5)(1) Regulation (EC) No. 1829/2003), Art. 34 TFEU in connection with Art. 4(3) TEU. See also ECJ, Case C-265/95, Commission ./. France, ECR 1997, p. 6959, para. 32.

[236] Art. 114(5) TFEU.

specific to that Member State".[237] Accordingly, Member States would have to produce scientific evidence that GM plants are as such inherently dangerous to human health and the environment because genetic engineering or genetic modification techniques respectively pose *per se* unique and hitherto unprecedented health and environmental risks. In fact, the Austrian 'Land' Oberösterreich (Upper Austria) failed to base its (draft) law prohibiting the cultivation of GMOs entirely on the TFEU's derogation clause.[238]

Admission of GMO in Food Production

Authorisation Requirement

The admission of GMOs in food production[239] is governed primarily by EU law which is complemented by national law as far as it concerns procedural aspects. EU law provides that GM food may be placed on the market on the basis of an authorisation only. This requirement of a marketing authorisation is laid down in Regulation (EC) No. 1829/2003.[240] Thus, GM food law does not follow the regulatory approach of general food law according to which food may be placed on the market without prior approval by a governmental authority, *i.e.* the person placing food on the market is fully and solely responsible that food safety requirements are fulfilled and consumers are not mislead.[241] GM food may need an additional authorisation granted on the basis of Regulation (EC) No. 258/97[242] "where they fall under one or more of the categories referred to in … Regulation (EC) No 258/97 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation".[243] Both regulations are directly applicable in Germany. Thus, the rules of the GenTG governing the placing on the market of products containing or consisting of GMOs[244] are inapplicable.[245]

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[237] Art. 114(5) TFEU.

[238] Court of First Instance, Joined Cases T-366/03 and T-235/04, Land Oberösterreich, ECR 2005, p. II-4005, para 36 et seq. This judgment was upheld by the ECJ, Joined Cases C-439/05 P and C-454/05 P, Land Oberösterreich, ECR 2007, p. I-7141, para. 60 et seq.

[239] In detail see, e.g., Nina Bergmann/Hans-Georg Dederer, in: Matthias Herdegen/Hans-Georg Dederer, Internationales Biotechnologierecht, EU-Recht/Erläuterungen, 5. Verordnung (EG) Nr. 1829/2003 (2012).

[240] Art. 4(2) Regulation (EC) No. 1829/2003.

[241] See Art. 14 Regulation (EC) No. 178/2002, Sec. 5, 11 LFGB, and Rudolf Streinz, Rechtliche Aspekte, in: Dieter Sturma/Dirk Lanzerath/Bert Heinrichs (eds.), Gentechnik in der Lebensmittelproduktion, 2011, p. 66.

[242] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.1997, p. 1.

[243] Recital 11 Regulation (EC) No. 1829/2003.

[244] Sec. 14 et seq. GenTG.

[245] Cf. Sec. 14(2) GenTG.

Scope of Application

The authorisation requirement of Regulation (EC) No. 1829/2003 applies only to GM food as defined for the purposes of the authorization requirement.[246] Therefore, the authorisation requirement covers GMOs as such for food use[247] (*e.g.*, GM tomatoes),[248] food containing or consisting of GMOs (*e.g.*, Pizza with GM tomatoes),[249] and food produced from GMOs (*e.g.*, GM tomato juice) or containing ingredients produced from GMOs (*e.g.*, Pizza with GM tomato purée).[250]

As a consequence, food produced 'with' GMOs is beyond the regulation's scope of application regarding the authorisation requirement.[251] Thus, GM processing aids (*e.g.*, GM Chymosin, *i.e.* Chymosin produced with the help of GM bacteria) or food produced with the help of GM processing aids (*e.g.*, cheese produced with GM Chymosin) are not covered by Regulation (EC) No. 1829/2003.[252] By the same token, milk from cows fed with GM plants is not subject to the regulation's authorisation requirement.[253] If, on the other hand, material from GMOs is present in the food, such food is considered GM food and, hence, covered by the market authorisation requirement under Regulation (EC) No. 1829/2003 even if the presence of the GMO or any GM material (*e.g.*, rDNA or proteins expressed by rDNA) is undetectable[254] (*e.g.*, in the case of sugar produced from GM sugar beet or soy bean oil

[246] See Art. 3(1) Regulation (EC) No. 1829/2003: GMOs for food use, food containing or consisting of GMOs, or food produced from or containing ingredients produced from GMOs. The term 'genetically modified food' as defined in Art. 2(6) Regulation (EC) No. 1829/2003 is restricted to "food containing, consisting of or produced from GMOs" only.

[247] Cf. also the legal definition of 'genetically modified organism for food use' in Art. 2(8) Regulation (EC) No. 1829/2003: "a GMO that may be used as food or as a source material for the production of food".

[248] Art. 3(1)(a) Regulation (EC) No. 1829/2003.

[249] Art. 3(1)(b) Regulation (EC) No. 1829/2003.

[250] Art. 3(1)(c) Regulation (EC) No. 1829/2003.

[251] Recital 16 Regulation (EC) No. 1829/2003; in detail Hans-Georg Dederer, Neues von der Gentechnik, Zeitschrift für das gesamte Lebensmittelrecht 2005, p. 307, at 310–312; see also Armin Werner/Bärbel Kniel/Udo Berg, DLR 2004, p. 165, at 167 et seq.; Marcus Girnau, Die neuen Regelungen zur Kennzeichnung und Rückverfolgbarkeit von gentechnisch veränderten Lebensmitteln (Verordnung [EG] Nr. 1829/2003 und 1830/2003), Zeitschrift für das gesamte Lebensmittelrecht 2004, p. 343, at 349 et seq.

[252] The production of GM processing aids with the help of GMMs constitutes contained use of GMOs. The contained use of GMMs is regulated by the GenTG which implements Directive 2009/41/EC. Accordingly, the production of, e.g., GM processing aids with GMMs in a fermenter would have to be classified usually only as a class 1-activitiy (Art. 4(3) Directive 2009/41/EC) or a safety level 1-activity (Sec. 7(1)(1)(1) GenTG) respectively. Thus, the production premise as well as the first contained use therein would have to be solely notified to the competent authority (Art. 6 Directive 2009/41/EC, Sec. 8(1)(1), (2)(1) GenTG). Subsequent class 1-activities or safety level 1-activities in the same premise could be carried out without any further notification (Art. 7(1) Directive 2009/41/EC, Sec. 9(1) GenTG).

[253] Recital 16 Regulation (EC) No. 1829/2003.

[254] See Recital 16 Regulation (EC) No. 1829/2003.

produced from GM soy beans).[255] In cases of doubt the European Commission may initiate a so called 'comitology procedure' for the purpose of clarifying whether a certain type of food is subject to the authorisation requirement.[256]

The placing on the market of food produced 'with' GMOs is also not subject to authorisation requirements under Directive 2001/18/EC and domestic law, *i.e.* the GenTG, implementing the Directive. The scope of the Directive's and the GenTG's authorisation requirements concerning the placing on the market is restricted to GMOs as or in products, *i.e.* products containing or consisting of GMOs,[257] or to products derived or produced from such GMOs which have been authorized for field trial purposes only.[258]

Whether an organism[259] is a GMO at all depends on the legal definition of 'GMO'. This definition of 'GMO' in a legal sense is laid down in Directive 2001/18/EC.[260] According to this definition, not all kinds of genetic modification give rise to a 'GMO' because some breeding techniques are not considered to result in 'genetic modification' within the meaning of EU genetic engineering law.[261] In addition, some organisms are not considered 'GMOs' within the meaning of Regulation (EC) No. 1829/2003 despite the fact that they were obtained through certain techniques considered to be genetic modification techniques.[262]

Substantive Authorisation Standards

The substantive standards GM food must meet in order to get an authorisation under Regulation (EC) No. 1829/2003 combine aspects of food safety (GM food "must not have adverse effects on human health … or the environment"),[263] consumer protection (GM food "must not mislead the consumer")[264] and, at least to a certain extent, food security (GM food "must not differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally

[255] See also Art. 2(10) Regulation (EC) No. 1829/2003 according to which 'produced from GMOs' means "derived, in whole or in part, from GMOs, but not containing or consisting of GMOs" as such. Cf. also Rudolf Streinz, Rechtliche Aspekte, in: Dieter Sturma/Dirk Lanzerath/Bert Heinrichs (eds.), Gentechnik in der Lebensmittelproduktion, 2011, p. 65.

[256] Art. 3(2) Regulation (EC) No. 1829/2003.

[257] Art. 13(1)(1) Directive 2001/18/EC; Sec. 14(1)(2)-(3) GenTG.

[258] Sec. 14(1)(4) GenTG; see Art. 6(9) Directive 2001/18/EC.

[259] As defined in Art. 2(4) Regulation (EC) No. 1829/2003 in connection with Art. 2(1) Directive 2001/18/EC.

[260] Art. 2(5) Regulation (EC) No. 1829/2003 in connection with Art. 2(2) Directive 2001/18/EC.

[261] See Annex I A, Part 2 Directive 2001/18/EC.

[262] See Art. 2(5) Regulation (EC) No. 1829/2003 in connection with Annex I B Directive 2001/18/EC.

[263] Art. 4(1)(a) Regulation (EC) No. 1829/2003.

[264] Art. 4(1)(b) Regulation (EC) No. 1829/2003.

disadvantageous to the consumer").[265] The substantive authorisation standards concerning human health and consumer protection correspond to the basic requirements concerning food safety and the prohibition to mislead consumers under general food law.[266] The food safety standard (*i.e.* GM food "must not have adverse effects on human health … or the environment") does, generally speaking, not allow for a risk-benefit analysis. This holds true without any exemption as far as health risks are concerned. On the other hand, environmental risks posed by the GMO may be balanced against environmental benefits deriving from the GMO (*e.g.*, within the context of its cultivation). The burden of proof that the GMO for food use or the food containing or consisting of GMOs or the food produced from or containing ingredients produced from GMOs meet the substantive authorisation standards and are, thus, eligible for a GM food authorisation lies with the applicant.[267]

Scope of GM Food Authorisation

A GM food authorisation may cover alternatively: (1) a GMO for food use as such plus foods containing or consisting of that GMO plus foods produced from or containing ingredients produced from that GMO, or (2) a food produced from a GMO plus foods produced from or containing that food, or (3) an ingredient produced from a GMO plus foods containing that ingredient.[268] If a GM product is likely to be used as both food and feed the applicant has to apply for a single authorisation.[269]

In addition, an authorisation granted on the basis of Regulation (EC) No. 1829/2003 may cover cultivation of the GMO as well even though GMO cultivation is regulated by Directive 2001/18/EC. In accordance with this so called 'one door, one key'-principle, the applicant applies for a GM food authorisation under the procedures set out in Regulation (EC) No. 1829/2003 which includes the authorisation for the cultivation of the GMO.[270]

Authorisation Procedure

The authorisation procedure starts with an application for authorisation. In theory, the applicant could be, *e.g.*, any food producer intending to place a GM food on the market. In practice, however, it is typically the seed company (like, *e.g.*, Monsanto or BASF) which submits the application required under Regulation (EC) No.

[265] Art. 4(1)(c) Regulation (EC) No. 1829/2003.

[266] See Art. 14, 16 Regulation (EC) No. 178/2002 and Rudolf Streinz, Rechtliche Aspekte, in: Dieter Sturma/Dirk Lanzerath/Bert Heinrichs (eds.), Gentechnik in der Lebensmittelproduktion, 2011, p. 65.

[267] Art. 4(3) Regulation (EC) No. 1829/2003.

[268] Art. 4(4) Regulation (EC) No. 1829/2003.

[269] See Art. 27 Regulation (EC) No. 1829/2003.

[270] See Recital 33, Art. 5(5), 6(3)(c), (4) Regulation (EC) No. 1829/2003.

1829/2003.[271] For it is the seed company which developed the GM crop line which, in turn, is characterized by the so called 'transformation event',[272] *i.e.* the specific genetic modification on the molecular level. Thus, the seed company is the only one in possession of all those data and information which have to be submitted for the purpose of demonstrating that the GM food conforms to the substantive standards laid down in Regulation (EC) No. 1829/2003.[273]

The application must be accompanied by an extensive dossier supporting the applicant's conclusion that the GM food complies with the substantive authorisation standards laid down in Regulation (EC) No. 1829/2003.[274] Thus, apart from the applicant's name and address,[275] the food's designation and specification[276] and a description of the production and manufacturing methods,[277] the application shall contain, *inter alia*, the transformation event[278] and methods of detecting, sampling and identification of the transformation event,[279] a copy of studies demonstrating that the GM food conforms to the substantive authorisation criteria,[280] and, where appropriate, a proposal for post-market monitoring regarding the use of the food for human consumption.[281] In the case of a GMO or food containing or consisting of GMOs, the applicant must provide (1) either a GM product authorisation granted under part C of Directive 2001/18/EC[282] or the technical dossier required for the purposes of a GM product authorisation under Directive 2001/18/EC and containing the risk assessment provided for by Directive 2001/18/EC, and (2) a monitoring plan for environmental effects in conformity with Directive 2001/18/EC.[283] If the GMO may be exported to third countries for direct use as food or for processing the applicant has to submit also the information specified in Annex II of the Cartagena Protocol and to be circulated among the other parties to the protocol.[284] In addition, the application must contain data and information concerning the conditions for placing on the market as well as specific conditions for use and handling,[285] furthermore, either an analysis showing that the GM food does not differ from its

[271] According to Art. 4(6) Regulation (EC) No. 1829/2003, the applicant has to be established in the European Union.

[272] In case of the GM maize line MON810, e.g., "MON810" denotes the transformation event.

[273] Cf., especially, Art. 4(3), 5(3), (5) Regulation (EC) No. 1829/2003.

[274] See Art. 5(3)-(5) Regulation (EC) No. 1829/2003.

[275] Art. 5(3)(a) Regulation (EC) No. 1829/2003.

[276] Art. 5(3)(b) Regulation (EC) No. 1829/2003.

[277] Art. 5(3)(d) Regulation (EC) No. 1829/2003.

[278] Art. 5(3)(b) Regulation (EC) No. 1829/2003.

[279] Art. 5(3)(i) Regulation (EC) No. 1829/2003.

[280] Art. 5(3)(e) Regulation (EC) No. 1829/2003.

[281] Art. 5(3)(k) Regulation (EC) No. 1829/2003.

[282] Implemented, in Germany, by Sec. 14 et seq. GenTG.

[283] Art. 5(5)(1) Regulation (EC) No. 1829/2003.

[284] See Art. 5(3)(c) Regulation (EC) No. 1829/2003 in connection with Art. 11(1)(1)-(2), Annex II Cartagena Protocol.

[285] Art. 5(3)(h) Regulation (EC) No. 1829/2003.

conventional counterparts or a proposal for a label indicating such difference,[286] and either a reasoned statement that the food is not expected to raise ethical or religious concerns or a labelling proposal pointing to such concerns.[287]

The application has to be submitted to the competent authority of an EU Member State,[288] *i.e.*, in Germany, to the BVL.[289] The BVL has to acknowledge receipt of the application within 14 days of its receipt, inform EFSA without delay, and pass the application and any further information supplied by the applicant to EFSA.[290] EFSA, in turn, has to inform the other EU Member States and the European Commission without delay and to circulate the application and any additional information supplied by the applicant among them.[291] In addition, EFSA must make the applicant's summary of his or her dossier[292] available to the public.[293]

Subsequently, EFSA has to prepare an expert opinion concerning, especially, the question whether the dossier is formally in accordance with the provisions of Regulation (EC) No. 1829/2003 and whether the GM food conforms to the substantive authorisation criteria.[294] The expert opinion must be also based on a food safety assessment[295] which may be carried out by a national authority,[296] *i.e.*, in Germany, by the BVL.[297] In addition, EFSA's opinion must be predicated on an environmental risk assessment. The environmental risk assessment may be carried out by a national authority which has been designated as competent authority for the purposes of executing general GMO law.[298] In Germany, it is the BVL which may be requested by EFSA to prepare the environmental risk assessment.[299] If the application also aims at the cultivation of the GMO EFSA is obliged to ask a national authority, *i.e.*, in Germany, again the BVL,[300] to carry out the environmental risk assessment.[301] If the application concerns a GMO or food containing or consisting of a GMO, the

[286] Art. 5(3)(f) Regulation (EC) No. 1829/2003.

[287] Art. 5(3)(g) Regulation (EC) No. 1829/2003.

[288] Art. 5(2)(1) Regulation (EC) No. 1829/2003.

[289] Sec. 1(1)(1) EGGenTDurchfG.

[290] Art. 5(2)(2)(a) Regulation (EC) No. 1829/2003.

[291] Art. 5(2)(2)(b)(i) Regulation (EC) No. 1829/2003.

[292] Cf. Art. 5(3)(l) Regulation (EC) No. 1829/2003.

[293] Art. 5(2)(2)(b)(ii) Regulation (EC) No. 1829/2003.

[294] Art. 6(3)(a) Regulation (EC) No. 1829/2003.

[295] Concerning food safety assessment, cf. also the guidance provided by the Codex Alimentarius Commission: WHO/FAO (ed.), Foods Derived from Biotechnology, 2nd ed., 2009.

[296] Art. 6(3)(b) Regulation (EC) No. 1829/2003. According to Art. 6(3)(b) Regulation (EC) No. 1829/2003, the national authority must be part of the networking provided for in Art. 36 Regulation (EC) No. 178/2002.

[297] Sec. 1(1)(2) EGGenTDurchfG.

[298] Art. 6(3)(c) Regulation (EC) No. 1829/2003 in connection with Art. 4(4)(1) Directive 2001/18/EC.

[299] Sec. 1(1)(3) EGGenTDurchfG.

[300] Sec. 1(1)(3) EGGenTDurchfG.

[301] Art. 6(3)(c) Regulation (EC) No. 1829/2003.

environmental risk assessment has to take into account the environmental safety requirements referred to in Directive 2001/18/EC.[302] Conforming to the requirements in Directive 2001/18/EC[303] serves the purpose of ensuring that all appropriate measures are taken to prevent adverse effects on human health or the environment. EFSA has to consult the national competent authorities designated by the Member States under Directive 2001/18/EC, *i.e.*, in Germany, the BVL,[304] which may submit opinions within 3 months after the date of receiving the request.[305] In addition, EFSA must verify the analysis provided by the applicant in order to show that the GM food does not differ from its conventional counterparts.[306] Finally, upon mandatory request by EFSA,[307] the Union reference laboratory (which has been established at the Joint Research Centre [JRC] in Ispra [Italy]) has to test and validate the method of detection and identification of the so called transformation event proposed by the applicant.

Thus, summing up, EFSA takes the following aspects into consideration: "molecular characterisation of the GM product, taking into account the characteristics of the donor and recipient organism; compositional, nutritional, and agronomic characteristics of the GM product; potential toxicity and allergenicity of the GM product; potential environmental impact following a deliberate release of the GM product and taking into account its intended uses either for import, processing or cultivation".[308]

If EFSA endorses the application, EFSA's opinion shall include, *inter alia*, the designation and specification of the GM food,[309] the information, if need be, required under Annex II to the Cartagena Protocol,[310] a labelling proposal,[311] any conditions or restrictions to be imposed on the placing on the market or specific conditions or restrictions for use and handling (including post-market monitoring requirements) and, in the case of GMOs or food containing or consisting of GMOs, conditions for the protection of particular ecosystems or geographical areas,[312] and, finally, the method for the detection and identification of the transformation event[313] and, if necessary, the monitoring plan for environmental effects.[314]

[302] Art. 6(4)(1) Regulation (EC) No. 1829/2003.

[303] Cf. Annex II, III and IV Directive 2001/18/EC.

[304] Sec. 1(1)(4) EGGenTDurchfG.

[305] Art. 6(4)(2)-(3) Regulation (EC) No. 1829/2003.

[306] Art. 6(3)(e) Regulation (EC) No. 1829/2003.

[307] Art. 6(3)(d) Regulation (EC) No. 1829/2003.

[308] http://www.efsa.europa.eu/en/topics/topic/gmo.htm

[309] Art. 6(5)(b) Regulation (EC) No. 1829/2003.

[310] Art. 6(5)(c) Regulation (EC) No. 1829/2003.

[311] Art. 6(5)(d) Regulation (EC) No. 1829/2003.

[312] Art. 6(5)(e) Regulation (EC) No. 1829/2003.

[313] Art. 6(5)(f) Regulation (EC) No. 1829/2003.

[314] Art. 6(5)(g) Regulation (EC) No. 1829/2003.

Concerning the preparation of its opinion, EFSA shall "endeavour" to respect a time limit of 6 months as from the receipt of a "valid" application.[315] EFSA, or any national authority through EFSA, may 'stop the clock' by asking the applicant to provide further scientific data or information (*e.g.*, study results) or any additional clarifications.[316] These interruptions of the authorisation process occur in the vast majority, *i.e.* in about 95 %,[317] of all cases. EFSA has to refer its opinion to the European Commission, to the Member States and to the applicant.[318] In addition, EFSA must make its opinion public.[319] Hence, a notice-and-comment-procedure starts: The public may make comments to the European Commission within a period of 30 days.[320]

EFSA's mission is not to authorize GM food but to give scientific advice to the Commission. Thus, risk assessment is carried out by EFSA whereas risk management is the Commission's task. Based on EFSA's opinion, the Commission draws up a draft decision within 3 months after having received EFSA's opinion.[321] If the draft deviates from EFSA's opinion, the Commission must come up with an explanation.[322] Apart from the opinion prepared by EFSA, the Commission may also take into account so called "other legitimate factors relevant to the matter under consideration".[323] In the light of general food law, *i.e.* Regulation (EC) No. 178/2002, such "other legitimate factors" might comprise socio-economic criteria, *e.g.*, "societal, economic, traditional, ethical … factors and the feasibility of controls".[324] For the purpose of identifying such "other legitimate factors", the Commission may draw on comments by the public[325] or, as far as it concerns ethical concerns, the Commission may ask the European Group on Ethics in Science and New Technologies for an opinion.[326]

If the Commission proposes to grant the market authorisation, its draft decision has to include the same contents as the favorable opinion produced by EFSA.[327] In addition, such a draft endorsing the placing on the market of the GM food has to

[315] Art. 6(1)(1) Regulation (EC) No. 1829/2003.

[316] Art. 6(1)(2), (2) Regulation (EC) No. 1829/2003.

[317] http://www.efsa.europa.eu/en/topics/topic/gmo.htm

[318] Art. 6(6) Regulation (EC) No. 1829/2003.

[319] Art. 6(7)(1) Regulation (EC) No. 1829/2003. Any information which the applicant has classed as confidential will be deleted, see Art. 6(7)(1) in connection with Art. 30 Regulation (EC) No. 1829/2003.

[320] Art. 6(7)(2) Regulation (EC) No. 1829/2003.

[321] Art. 7(1)(1) Regulation (EC) No. 1829/2003.

[322] Art. 7(1)(2) Regulation (EC) No. 1829/2003.

[323] Art. 7(1)(1) Regulation (EC) No. 1829/2003.

[324] Recital 19 Regulation (EC) No. 178/2002; see Hans-Georg Dederer, Weiterentwicklung des Gentechnikrechts – GVO-freie Zonen und sozioökonomische Kriterien der GVO-Zulassung, 2010, p. 189 et seq.

[325] See Art. 6(7)(2) Regulation (EC) No. 1829/2003.

[326] See Art. 33(1) Regulation (EC) No. 1829/2003.

[327] Art. 7(2) in connection with Art. 6(5) Regulation (EC) No. 1829/2003.

mention the name of the authorisation-holder and, as the case may be, the so called 'unique identifier' attributed to the GMO.[328] The unique identifier is "a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorized transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO".[329]

The draft decision is processed within the framework of the so called 'comitology procedure'.[330] The comitology procedure works as follows: The Commission has to submit the draft to the Standing Committee of the Food Chain and Animal Health[331] within 3 months after having received the expert opinion by EFSA.[332] This committee is composed of experts[333] who are, at the same time, representatives of the Member States.[334] If the committee agrees with the Commission's draft decision, the Commission has to adopt that decision.[335] If the committee disagrees with the Commission's draft decision, or if the committee does not reach any conclusion, the draft has to be forwarded to the Council of Ministers.[336] If the Council adopts the Commission's proposal, it is the Council which takes the final decision granting market authorisation of the GM food.[337] If the Council, within a period of up to 3 months, has neither adopted any position nor rejected the Commission's proposal, the Commission must take its proposed decision.[338] If the Council, acting by a qualified majority, opposes the draft decision submitted by the Commission, the Commission must choose between reexamining its draft, submitting an amended draft or re-submitting its original draft.[339] The comitology procedure is highly politicized because it involves the Standing Committee of the Food Chain and Animal

[328] Art. 7(2) Regulation (EC) No. 1829/2003.

[329] Art. 3(4) Regulation (EC) No. 1830/2003. E.g., the unique identifier of the GM maize line MON810 is MON-00810-6 (see http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=11).

[330] Cf. Art. 7(3) Regulation (EC) No. 1829/2003.

[331] See Art. 7(3) in connection with 35(1) Regulation (EC) No. 1829/2003.

[332] Art. 35(2)(1) Regulation (EC) No. 1829/2003 in connection with Art. 5(2)(1) Decision 1999/468/EC.

[333] Rudolf Streinz, Rechtliche Aspekte, in: Dieter Sturma/Dirk Lanzerath/Bert Heinrichs (eds.), Gentechnik in der Lebensmittelproduktion, 2011, p. 69.

[334] Art. 58(1)(1) Regulation (EC) No. 178/2002; Art. 35(2)(1) Regulation (EC) No. 1829/2003 in connection with Art. 5(1) Decision 1999/468/EC.

[335] Art. 35(2)(1) Regulation (EC) No. 1829/2003 in connection with Art. 5(3) Decision 1999/468/EC.

[336] Art. 35(2)(1) Regulation (EC) No. 1829/2003 in connection with Art. 5(4) Decision 1999/468/EC.

[337] Art. 35(2)(1) Regulation (EC) No. 1829/2003 in connection with Art. 5(6)(1) Decision 1999/468/EC; see Rudolf Streinz, Rechtliche Aspekte, in: Dieter Sturma/Dirk Lanzerath/Bert Heinrichs (eds.), Gentechnik in der Lebensmittelproduktion, 2011, p. 69.

[338] Art. 35(2)(1) Regulation (EC) No. 1829/2003 in connection with Art. 5(6)(3) Decision 1999/468/EC.

[339] Art. 35(2)(1) Regulation (EC) No. 1829/2003 in connection with Art. 5(6)(2) Decision 1999/468/EC.

Health, which is made up of representatives from the Member States who are, or, at least, can be, bound by instructions of their respective governments. In addition, in the field of GM food authorisation, the comitology procedure usually also involves the Council which is composed of ministers, *i.e.* politicians. Despite the political character of the comitology procedure,[340] the European Parliament is not actively involved in the decision-making process concerning the authorisation of GM food but is, in practice, reduced to being informed only.[341]

After a decision has been taken, the Commission must inform the applicant without delay and publish details of the decision in the Official Journal of the EU.[342] Despite the fact that time limits are set for most of the steps of the authorisation procedure, the duration of the whole process is more or less unpredictable.

In case of a favourable outcome, the market authorisation is granted for an initial period of 10 years being valid throughout the Union.[343] It is afterwards renewable for 10-year periods.[344] The procedure for the renewal of market authorisations is identical with the procedure aiming at the authorisation of GM food for the first time.[345] However, the compilation of the application dossier seems to be less burdensome.[346] The dossier has to include, *inter alia*, a monitoring report (as far as monitoring was required under the original market authorisation),[347] new information concerning the food safety assessment and any risks to human health or the environment,[348] and, as the case may be, a proposal for additional conditions of the original authorisation.[349]

Threshold Values

Currently, two kinds of legal threshold values are applicable in the EU and, thus, also in Germany.

[340] See also Rudolf Streinz, Rechtliche Aspekte, in: Dieter Sturma/Dirk Lanzerath/Bert Heinrichs (eds.), Gentechnik in der Lebensmittelproduktion, 2011, p. 69–70.

[341] Art. 35(2)(1) Regulation (EC) No. 1829/2003 in connection with Art. 5(4), (5), Art. 8 Decision 1999/468/EC.

[342] Art. 7(4) Regulation (EC) No. 1829/2003.

[343] Art. 7(5) Regulation (EC) No. 1829/2003.

[344] Art. 11(1) Regulation (EC) No. 1829/2003.

[345] Cf. Art. 11(3) Regulation (EC) No. 1829/2003.

[346] See Art. 11(2) Regulation (EC) No. 1829/2003.

[347] Art. 11(2)(b) Regulation (EC) No. 1829/2003.

[348] Art. 11(2)(c) Regulation (EC) No. 1829/2003.

[349] Art. 11(2)(d) Regulation (EC) No. 1829/2003.

Labelling Thresholds

The 0.9 %-threshold applies to GM specific labelling of GM food.[350] According to Regulation (EC) No. 1829/2003, GM specific labelling is not required if food contains "material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable".[351] Thus, if the food consists of multiple ingredients the 0.9 %-threshold applies to each ingredient individually. The same threshold applies to "products intended for direct use as food or … for processing".[352] If the labelling threshold of 0.9 % is exceeded the respective food is subject to the GM specific labelling requirements.

Authorisation Thresholds

The 0.1 %-threshold applies to feed only. Like GM food, GM feed may not be placed on the market unless on the basis of a market authorisation issued in accordance with Regulation (EC) No. 1829/2003.[353] However, according to Regulation (EU) No. 619/2011, feed with traces of GM material[354] below the threshold of 0.1 % does not trigger the market authorisation requirement under Regulation (EC) No. 1829/2003 if the GM material meets certain requirements.[355] Nevertheless, Member States have to record such test results and must notify the European Commission as well as the other member States by the 30th of June each year.[356] The Commission or any Member State may, if need be, adopt emergency measures in accordance with Regulation (EC) No. 178/2002.[357] If the 0.1 %-threshold is exceeded or if the detected GM material does not conform to the specific requirements laid down in Regulation (EC) No. 612/2011, the respective feed has to be considered non-compliant with Regulation (EC) No. 1829/2003.[358] This means that the feed must

[350] GM specific labelling means that the label has to indicate explicitly that, e.g., the food is "genetically modified" or "contains GMOs". See Art. 13(1) Regulation (EC) No. 1829/2003 and infra at section "Labelling" (in and at fn. 421–424).

[351] Art. 12(2) Regulation (EC) No. 1829/2003.

[352] Art. 4(8) Regulation (EC) No. 1830/2003.

[353] Art. 16(2) Regulation (EC) No. 1829/2003.

[354] Meaning, in this case, "material which contains, consists of or is produced from GMOs", Art. 1(1)(3) Regulation (EU) No. 619/2011.

[355] See, in detail, Art. 2 Regulation (EU) No. 619/2011.

[356] Art. 6(2)(1) Regulation (EU) No. 619/2011.

[357] Recital 18 and Art. 6(3) Regulation (EU) No. 619/2011 in connection with Art. 53, 54 Regulation (EC) No. 178/2002.

[358] Art. 6(1)(1), Annex II B 2 Regulation (EU) No. 619/2011.

not be placed on the market because it lacks the market authorisation required under Regulation (EC) No. 1829/2003.[359]

Since 18 April 2007, the 0.5 %-threshold laid down in Regulation (EC) No. 1829/2003 is no longer applicable.[360] According to a transitional provision, 'conventional' food was not subject to the market authorisation requirement neither under Regulation (EC) No. 1829/2003[361] nor under Directive 2001/18/EC[362] if material which contained, consisted of or was produced from GMOs in a proportion no higher than 0.5 % was present in the food and if these GM traces conformed to certain requirements.[363]

Implementation and Enforcement, Controlling Regime

Implementation and Enforcement

Under Regulation (EC) No. 1829/2003, the applicant may choose in which Member State he or she would like to file his or her application for market authorisation of GM food.[364] In Germany, the application has to be submitted to the BVL.[365] The BVL is also the national competent authority which may ask the applicant, through EFSA, to provide additional data or information,[366] which may be asked to carry out the food safety assessment[367] or the environmental risk assessment[368] and which may be consulted by EFSA with regard to environmental safety standards.[369]

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[359] Art. 16(2) Regulation (EC) No. 1829/2003.

[360] See Art. 47(5) in connection with Art. 49 (5) Regulation (EC) No. 1829/2003; Art. 12a(2) Directive 2001/18/EC.

[361] Art. 4(2) Regulation (EC) No. 1829/2003.

[362] Art. 13(1)(1) Directive 2001/18/EC.

[363] See Art. 47(1) Regulation (EC) No. 1829/2003; Art. 12a(1) Directive 2001/18/EC.

[364] Cf. Art. 5(2)(1) Regulation (EC) No. 1829/2003.

[365] Sec. 1(1)(1) EGGenTDurchfG.

[366] Sec. 1(1)(1) EGGenTDurchfG in connection with Art. 6(2) Regulation (EC) No. 1829/2003.

[367] Sec. 1(1)(2) EGGenTDurchfG in connection with Art. 6(3)(b) Regulation (EC) No. 1829/2003. For the purposes of its opinion, the BVL has to consult both the Robert Koch-Institut and the Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment), Sec. 3(1) EGGenTDurchfG.

[368] Sec. 1(1)(3) EGGenTDurchfG in connection with Art. 6(3)(c) Regulation (EC) No. 1829/2003. For the purposes of its opinion, the BVL has to consult both the Bundesamt für Naturschutz (Federal Agency for Nature Conservation) and the Robert Koch-Institut, Sec. 3(2)(1) EGGenTDurchfG. In addition, the BVL has to ask the Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment), the Bundesfoschungsinstitut für Kulturpflanzen (Federal Research Centre for Cultivated Plants) and, if need be, the Bundesforschungsinstitut für Tiergesundheit (Federal Research Institute for Animal Health) for their expert opinions, Sec. 3(2)(2) EGGenTDurchfG.

[369] Sec. 1(1)(4) EGGenTDurchfG in connection with Art. 6(4)(3) Regulation (EC) No. 1829/2003. For the purposes of its opinion, the BVL has to consult both the Bundesamt für Naturschutz

Both the holder of a market authorisation and all "parties concerned" have to abide by the conditions and restrictions laid down in the authorisation.[370] The term "parties concerned" is not defined in Regulation (EC) No. 1829/2003. It includes all persons who are "operators" within the meaning of Regulation (EC) No. 1830/2003, *i.e.* natural or legal persons who place a GM food on the market or who receive a GM food that has been placed on the market in the Union at any stage of the production and distribution chain.[371] In addition, "parties concerned" are those persons who 'use' or 'handle' the GM food. In any case, however, final consumers of the GM food are excluded.[372] On the other hand, farmers belong to the group of "parties concerned" if the authorisation also covers cultivation in accordance with the 'one door, one key'-principle.[373]

The market authorisation of a GM food must oblige the authorisation-holder to monitor the environmental effects (if the authorisation covers GMOs or food containing or consisting of GMOs)[374] and may impose on the authorisation-holder the obligation to monitor the use of the GM food for human consumption.[375] The authorisation-holder has to ensure that the monitoring is carried out in accordance with the monitoring plans.[376]

The holder of a market authorisation is subject to certain reporting requirements. Especially, authorisation-holders have to submit monitoring reports to the Commission.[377] These monitoring reports have to be made available to the public after any information acknowledged to be confidential has been deleted.[378] In addition, the authorisation-holder has to inform the Commission of any new scientific or technical information affecting the food safety assessment.[379] Of particular

(Federal Agency for Nature Conservation) and the Robert Koch-Institut, Sec. 3(2)(1) EGGenTDurchfG. In addition, the BVL has to ask the Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment), the Bundesfoschungsinstitut für Kulturpflanzen (Federal Research Centre for Cultivated Plants) and, if need be, the Bundesforschungsinstitut für Tiergesundheit (Federal Research Institute for Animal Health) for their expert opinions, Sec. 3(2)(2) EGGenTDurchfG.

[370] Art. 9(1)(1) Regulation (EC) No. 1829/2003.

[371] See Art. 3(5) Regulation (EC) No. 1830/2003.

[372] See Art. 3(5) Regulation (EC) No. 1830/2003.

[373] See supra at section "Admission of GMO in food production" (in and at fn. 270).

[374] Recital 35 cl. 2 ("compulsory"), Art. 9(1)(2) in connection with Art. 5(5)(1)(b), 6(5)(e) Regulation (EC) No. 1829/2003; Art. 19(3)(f) Directive 2001/18/EC.

[375] Recital 35 cl. 1, Art. 9(1)(2) in connection with Art. 5(3)(k), 6(5)(e) Regulation (EC) No. 1829/2003.

[376] Art. 9(1)(2) Regulation (EC) No. 1829/2003.

[377] Art. 9(1)(2) Regulation (EC) No. 1829/2003. See also Sec. 21(4a) GenTG which imposes a corresponding reporting requirement on the authorisation-holder vis-à-vis the BVL.

[378] Art. 9(1)(3) Regulation (EC) No. 1829/2003.

[379] Art. 9(3)(1) Regulation (EC) No. 1829/2003. See also Sec. 21(5) GenTG. See additionally Sec. 21(3)(1) GenTG according to which the authorisation-holder has to inform the Commission and the competent German authorities without delay of any incident which does not correspond to the expected course of the placing on the market of a GMO if the incident is suspected of endangering human health or the environment. See furthermore Sec. 21(5a) GenTG which provides that the

importance in this regard are restrictions or even prohibitions imposed by third countries in which the GM food is, or has been, also placed on the market.[380] Any such new information has to be forwarded to EFSA and the Member States by the Commission without delay.[381]

The Commission or, in Germany, the BVL may ask EFSA to prepare an opinion on whether a market authorisation still meets the requirements laid down in Regulation (EC) No. 1829/2003.[382] EFSA has to pass on its opinion to the Commission, the authorisation-holder and the Members States.[383] In addition, EFSA's opinion has to be made accessible to the public which may, within the context of a 30 day notice-and-comment-procedure, make comments.[384] Depending on the final outcome, the authorisation may have to be modified, suspended or even revoked.[385] If any modification or suspension of an authorisation is urgently needed, the Commission or a Member State, *i.e.*, in Germany, the BVL, may adopt emergency measures.[386] According to the EGGenTDurchfG, the BVL is explicitly entitled to provisionally suspend a market authorisation issued under Regulation (EC) No. 1829/2003 in full or in part.[387] As long as the BVL remains inactive, the competent authorities of the German States ('Länder') may take interim protective measures.[388] In particular, they are explicitly granted the power to enjoin the placing on the market of GM foods provisionally.[389]

If GM material not authorized in the EU is present in food, the Commission or the Member States may impose emergency safeguard measures, *e.g.*, the provisional prohibition of the placing on the market of the relevant food product. Examples include the Commission's decision concerning the non-authorised GMO Bt10 in maize products[390] and its decision concerning the non-authorised GMO LL RICE 601 in rice products.[391]

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authorisation-holder has to report to the BVL any new information on risks to human health or the environment or to coexistence.

[380] Art. 9(3)(2) Regulation (EC) No. 1829/2003.

[381] Art. 9(4) Regulation (EC) No. 1829/2003.

[382] Art. 10(1)(1) Regulation (EC) No. 1829/2003; Sec. 1(1)(5) EGGenTDurchfG.

[383] Art. 10(1)(2) Regulation (EC) No. 1829/2003.

[384] Art. 10(1)(3)-(4) Regulation (EC) No. 1829/2003.

[385] Art. 10(2)(2) Regulation (EC) No. 1829/2003.

[386] See Art. 10(2)(2), 34 Regulation (EC) No. 1829/2003 in connection with Art. 53, 54 Regulation (EC) No. 178/2002.

[387] Sec. 1(2) EGGenTDurchfG in connection with Art. 34 Regulation (EC) No. 1829/2003, Art. 54 Regulation (EC) No. 178/2002.

[388] Sec. 4(2)(1) EGGenTDurchfG in connection with Art. 34 Regulation (EC) No. 1829/2003, Art. 54 Regulation (EC) No. 178/2002.

[389] Sec. 4(2)(2) EGGenTDurchfG.

[390] Commission Decision of 18 April 2005 on emergency measures regarding the non-authorised genetically modified organism Bt10 in maize products (2005/317/EC) (OJ L 101, 21.4.2005, p. 14).

[391] Commission Decision of 5 September 2006 on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products (2006/601/EC) (OJ L 244, 7.9.2006, p. 27).

Controlling Regime

Notwithstanding the powers attributed to the BVL and outlined above, the competence of controlling compliance with Regulations (EC) No. 1829/2003, 1830/2003 and 1946/2003 lies with the German States ('Länder').[392] Besides provisional safeguard measures,[393] the competent State authorities enjoy extensive powers under general German food law for the purpose of controlling adherence to Regulations (EC) No. 1829/2003, 1830/2003 and 1946/2003 with regard to GM food.[394] Their public officials may, *e.g.*, enter real property, premises and means of transport and take pictures of them, inspect and copy documents and electronic data, request information, and take samples.[395] The owners or occupants of the real property, premises and transportation means are obliged to support the public officials in their exercise of functions.[396]

Labelling Regime

Labelling

Labels Declaring Food Free of GMOs

The use of labels declaring food free of GMOs is, in principle, not prohibited by EU law. Domestic rules on food labels pointing explicitly to the food's being free of GMOs must conform to EU law, in particular to the law on the free movement of goods,[397] though.[398]

In Germany, food free of GMOs may be labelled "ohne Gentechnik" ("without genetic engineering") only, *i.e.* other labels, *e.g.*, "gentechnikfrei" ("genetic engineering free") are prohibited.[399] The label "ohne Gentechnik" signifies that the food has been produced without the use of genetic engineering techniques.[400] Accordingly, food labelled "ohne Gentechnik" must meet strict requirements.

In particular, the food must be produced without the use of foods or food ingredients covered by the labelling requirements of Regulation (EC) No. 1829/2003 or

[392] Sec. 4(1) EGGenTDurchfG.

[393] See Sec. 4(2) EGGenTDurchfG.

[394] Sec. 4(3)(a) EGGenTDurchfG in connection with Sec. 38, 39(1), (2) and (7), 40, 42–44 LFGB.

[395] See Sec. 42(2)(1) LFGB.

[396] See Sec. 44(1) LFGB.

[397] Art. 34 et seq. TFEU.

[398] Rudolf Streinz, Rechtliche Aspekte, in: Dieter Sturma/Dirk Lanzerath/Bert Heinrichs (eds.), Gentechnik in der Lebensmittelproduktion, 2011, p. 80.

[399] Sec. 3a(1)(2) EGGenTDurchfG.

[400] Cf. Sec. 3a(1)(1) EGGenTDurchfG.

Regulation (EC) No. 1830/2003.[401] This prohibition also applies to the use of foods or food ingredients which are only 'contaminated' with GM material even if the GM traces are adventitious and technically unavoidable and do not exceed the 0.9 %-threshold.[402] Moreover, for the purposes of preparing, treating, processing and blending of foods or food ingredients, foods, food ingredients, processing aids or additives[403] must not have been produced with, or by, GMOs or GMMs.[404] This prohibition does not apply if the food, food ingredient, processing aid or additive produced with, or by, GMOs or GMMs is covered by a waiver granted by the European Commission under Regulation (EC) Nr. 834/2007 on organic production and labelling of organic products.[405]

As far as it concerns foods or food ingredients derived from animals, animals must not have been fed on GM feed governed by the labelling requirements of Regulation (EC) No. 1829/2003 or Regulation (EC) No. 1830/2007. This prohibition does not apply to feed with adventitious and technically unavoidable GM traces no higher than the threshold of 0.9 %.[406] Furthermore, the prohibition to feed animals on GM feed is restricted to a certain period of time before the start of the food production process.[407] Thus, *e.g.*, the feeding of pigs on GM feed must be terminated 4 months before slaughtering.[408] What is more, the use of feed additives produced with, or by, GMMs, *e.g.*, vitamins (*e.g.*, B2), amino acids (*e.g.*, Lysine) and enzymes (*e.g.*, Amylase), does not preclude the use of the "ohne Gentechnik"-label.[409] The same holds true if the animals have been treated with veterinary GM drugs or GM vaccines.[410]

The label "ohne Gentechnik" may be affixed only if it is established by supporting documents that the aforementioned prerequisites have been met.[411]

Law on the Use of GMOs for Organic Food

Production of organic food is covered by EU law, *i.e.* by Regulation (EC) No. 834/2007. The Regulation explicitly states that "[g]enetically modified organisms (GMOs) and products produced from or by GMOs are incompatible with the concept of organic production and consumers' perception of organic products."[412]

[401] Sec. 3a(2) EGGenTDurchfG.

[402] Sec. 3a(3) EGGenTDurchfG.

[403] Within the meaning of Sec. 5(2) LMKV.

[404] Sec. 3a(5)(1) EGGenTDurchfG.

[405] Sec. 3a(5)(2) EGGenTDurchfG.

[406] Sec. 3a(4)(1) EGGenTDurchfG.

[407] Sec. 3a(4)(2) EGGenTDurchfG.

[408] See Annex to Sec. 3a(4)(2) EGGenTDurchfG.

[409] http://www.transgen.de/recht/kennzeichnung/280.doku.html

[410] http://www.transgen.de/recht/kennzeichnung/280.doku.html

[411] See Sec. 3b EGGenTDurchfG.

[412] Recital 9 cl. 1.

Therefore, "[t]he use of GMOs in organic production is prohibited."[413] Consequently, with the exception of veterinary medicinal products (*e.g.*, drugs, vaccines), the use of GMOs as well as the use of products produced from or by GMOs is not allowed.[414] This prohibition applies to GMOs or products produced from or by GMOs used as food, feed, processing aids, plant protection products, fertilizers, soil conditioners, seeds, vegetative propagating material, micro-organisms and animals.[415] For the purposes of this prohibition, operators, *e.g.*, farmers, may rely on the labels affixed to, or the documents accompanying, the products (*e.g.*, seeds).[416] Accordingly, farmers producing organic food or organic food commodities might unwittingly use products containing GM traces which are adventitious and technically unavoidable and no higher than the 0.9 %-threshold. In such cases, terms like 'bio' or 'eco' may still be used in the labelling of such organic products.[417] However, the European Commission may issue a waiver permitting the use of food or feed additives or other substances produced by GMOs if conventional substances are not available on the market.[418] This waiver does not extend to the labelling of organic products, though.[419] Thus, if food derived from organic production has to be labelled in accordance with Directive 2001/18/EC, Regulation (EC) No. 1829/2003 or Regulation (EC) No. 1830/2003 indicating that the food contains or consists of GMOs or is produced from GMOs, terms like 'bio' or 'eco' must not be used for such food.[420]

Contents of Food Labelling Law Concerning the Use of GMO

Usually, GM specific labelling is obligatory for GM food covered by Regulation (EC) No. 1829/2003, *i.e.* GM food must be labelled using terms such as 'genetically modified', 'produced from genetically modified (name of organism/ingredient)', 'contains genetically modified (name of organisms)' or 'contains (name of ingredient) produced from genetically modified (organisms)'.[421] These terms have to appear in the list of ingredients[422] if the food consists of more than one ingredi-

[413] Recital 30 cl. 1; Art. 4(a)(iii).

[414] Art. 4(a)(iii) Regulation (EC) No. 834/2007.

[415] Art. 9(1) Regulation (EC) No. 834/2007.

[416] See 9(2) Regulation (EC) No. 834/2007.

[417] Cf. Recital 10, Art. 23(1) Regulation (EC) No. 834/2007.

[418] Art. 22(2)(g) Regulation (EC) No. 834/2007.

[419] Cf. Art. 22(1) Regulation (EC) No. 834/2007 ("exceptions from the production [sic!] rules").

[420] Recital 30 cl. 2, Art. 23(3) Regulation (EC) No. 834/2007.

[421] Cf. Art. 13(1)(a)-(c) Regulation (EC) No. 1829/2003.

[422] The term 'ingredient' includes additives and enzymes used in the manufacture or preparation of food and still present in the finished product, even if in altered form (Art. 2(13) Regulation (EC) No. 1839/2003 in connection with Art. 6(4)(a) Directive 2000/13/EC). Thus, foods containing additives produced from GM plants, e.g., Lecithin from GM soybeans, are subject to the labelling requirements of Art. 12 et seq. Regulation (EC) No. 1829/2003. On the other hand, foods containing additives produced from GM plants and used as processing aids only, need not be labeled in accordance with Art. 12 et seq. Regulation (EC) No. 1829/2003 (see Art. 2(13) Regulation (EC) No. 1829/2003 in connection with Art. 6(4)(c)(ii) Directive 2000/13/EC).

ent.[423] If the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers, the aforementioned terms must be permanently and visibly displayed on the food display or immediately next to it or on the packing material.[424] Under Regulation (EC) No. 1829/2003, GM specific labelling is irrespective of whether DNA or proteins resulting from the genetic modification are detectable in the food.[425]

The aforementioned GM specific labelling requirements do not apply to all GM foods. Rather, they are confined to GM foods which are to be delivered as such to the final consumer or to mass caterers (*e.g.*, restaurants, hospitals or canteens).[426] In addition, concerning the labelling requirements, GM foods are defined as foods which contain or consist of GMOs or which are produced from or contain ingredients produced from GMOs.[427] Thus, the scope of the GM specific labelling requirements and the scope of the authorisation requirement seem not to be congruent because GM specific labelling does seemingly not extend to "GMOs for food use".[428] Nevertheless, *a minore ad maius*, also GMOs for food use have to be GM specifically labelled in accordance with Regulation (EC) No. 1829/2003.[429]

Thus, by way of example, GM tomatoes have to be labelled 'genetically modified'. In the case of pizza with GM tomatoes, the list of ingredients has to mention the ingredient "tomato (genetically modified)". On the label of GM tomato juice the terms "produced from genetically modified tomatoes" has to appear. The list of ingredients of pizza with GM tomato purée has to declare that the pizza "contains tomato purée produced from genetically modified tomatoes".

As far as it concerns labelling at earlier stages of the production and distribution chain, operators[430] have to ensure that for pre-packaged products consisting of or containing GMOs the words "This product contains genetically modified organisms" or "This product contains genetically modified (name of organism(s))" appear on a label.[431] Concerning products for food produced from GMOs, operators placing the product on the market have to ensure that GM specific information is transmitted in writing to the operators receiving the product. According to this traceability require-

[423] Art. 13(1)(a), (b), (d) Regulation (EC) No. 1829/2003.

[424] Art. 13(1)(e) Regulation (EC) No. 1829/2003.

[425] Recital 21 cl. 2 Regulation (EC) No. 1829/2003.

[426] Art. 2(16), 12(1) Regulation (EC) No. 1829/2003 in connection with Art. 1(2) Directive 2000/13/EC. As a consequence, e.g., GM foods delivered by mass caterers to final consumers are not subject to GM specific labelling if the foods have been prepared or processed (Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, COM/2006/0626 final, p. 28).

[427] Art. 12(1) Regulation (EC) No. 1829/2003.

[428] Cf. Art. 3(1) and 12(1) Regulation (EC) No. 1829/2003.

[429] See also http://www.transgen.de/recht/kennzeichnung/278.doku.html

[430] I.e. natural or legal persons who place a product on the market or who receive a product that has been placed on the market in the European Union, either from a Member State or from a third country, at any stage of the production and distribution chain (Art. 3(5) Regulation (EC) No. 1830/2003).

[431] Art. 4(6)(a) Regulation (EC) No. 1830/2003.

ment, the following information has to be transmitted: an indication of each of the food ingredients which is produced from GMOs, or, in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.[432]

In addition, the aforementioned labelling (and traceability) requirements do not apply to foods (and products for food produced from GMOs) containing GM material in a proportion no higher than 0.9 % of the food ingredients considered individually or food consisting of a single ingredient.[433] This 0.9 %-threshold is applicable only if the presence of GM traces is adventitious or technically unavoidable.[434] Operators may avail themselves of the threshold provided that they are able to demonstrate that they have taken appropriate steps to avoid the presence of traces of GM material, *i.e.* material which contains, consists of or is produced from GMOs.[435]

The GM specific labelling requirements are complemented by labelling requirements related to the novelties of GM foods. If the GM food does not have a conventional counterpart the food's label shall provide information about its nature and characteristics.[436] If, on the contrary, the GM food does have a conventional counterpart but differs from it with regard to composition, nutritional value, nutritional effects, intended use or health implications (*e.g.*, allergenicity), the market authorisation has to specify the characteristics or properties to be mentioned on the food label.[437] The same applies if the food gives rise to ethical or religious concerns (on grounds of, *e.g.*, dietary laws).[438]

Legislation Addressing Labelling Fraud

The labelling of GM foods has to comply with the general labelling requirements laid down in Directive 2001/13/EC[439] which has been implemented into German law by the LMKV. Thus, labelling of GM foods must not mislead the purchaser.[440] The same applies to non-GM food which must not be labeled in a misleading way. Therefore, *e.g.*, GM free labelling may be considered misleading if all similar foods possess the same characteristic of being GM free because the food category concerned

[432] Art. 5(1)(a), (c) Regulation (EC) No. 1830/2003.

[433] Thus, if the food consists of more than one ingredient, the 0.9 %-threshold applies to each ingredient individually. See Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, COM/2006/0626 final, p. 27.

[434] Art. 12(2) Regulation (EC) No. 1829/2003; Art. 4(8), 5(3) Regulation (EC) No. 1830/2003.

[435] Art. 12(3) Regulation (EC) No. 1829/2003.

[436] Art. 13(3) Regulation (EC) No. 1829/2003.

[437] Art. 13(2)(a) Regulation (EC) No. 1829/2003.

[438] Art. 13(2)(b) Regulation (EC) No. 1829/2003.

[439] See Recital 18 Regulation (EC) No. 1829/2003.

[440] Cf. Art. 2(1) Directive 2000/13/EC; Sec. 11(1) LFGB.

has not been genetically modified hitherto.[441] *E.g.*, GM free labelling of beer would be misleading. For, currently, it is a matter of course that beer is GM free because neither GM barley nor GM wheat nor GM yeast is placed on the market.[442]

With regard to the German "ohne Gentechnik"-label, however, one could argue that this label does not only guarantee a GM free contents of the product but also a GM free production and distribution chain. Thus, in case of food which could have been 'contaminated' with GM material in the course of the (international) production or distribution chain, the label "ohne Gentechnik" does not point to a characteristic which is self-evident.[443]

GM free labelling which is not in conformity with the EGGenTDurchfG is punishable.[444] The same holds true in case of misleading labelling.[445] Violations of labelling rules under Regulation (EC) No. 1829/2003 and Regulation (EC) No. 1830/2003 constitute administrative offences.[446] Misleading labelling can be considered unfair competition as well. Thus competitors could file for injunctive relief on the basis of the Law against Unfair Competition (Gesetz gegen unlauteren Wettbewerb – UWG).[447,448]

Liability

Genetic Technology

Legal Nature of Liability Law Governing Genetic Technology

The liability law governing genetic engineering is in part civil law, in part criminal law and in part administrative law.

[441] Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, COM/2006/0626 final, p. 28.

[442] Cf. Sec. 11(1)(3) LFGB.

[443] Cf. Oberverwaltungsgericht Koblenz, Zeitschrift für das gesamte Lebensmittelrecht, 2003, p. 750, at 752 et seq.

[444] Sec. 6(3a) EGGenTDurchfG.

[445] Sec. 59(1)(7), (1)(9) LFGB.

[446] See Sec. 7(2)(4), (3)(3) EGGenTDurchfG in connection with Art. 12(1), 13(1), (2)(a) Regulation (EC) No. 1829/2003 and Art. 4(6)(1) Regulation (EC) No. 1830/2003.

[447] Gesetz gegen den unlauteren Wettbewerb (BGBl. 2010 I p. 254), last amended by law of 1 October 2013 (BGBl. 2013 I p. 3714).

[448] See Sec. 3(1) UWG.

Conditions for Liability

Criminal and Administrative Liability

Both Regulation (EC) No. 1829/2003 and Regulation (EC) Nr. 1830/2003 stipulate that the EU Member States shall lay down the rules on penalties applicable to infringements of the regulations' provisions. In particular, the penalties provided for must be effective, proportionate and dissuasive.[449] In Germany, such penalties have been laid down in the EGGenTDurchfG which provides for both criminal and administrative offences.

According to the EGGenTDurchfG, the placing on the market of GM foods without prior authorisation in accordance with Regulation (EC) No. 1829/2003[450] will be punished by imprisonment of up to 3 years or a fine,[451] in case of negligence by imprisonment of up to 1 year or a fine.[452] If the placing on the market of unauthorized GM food endangers the life or health of others or objects of great value belonging to someone else or components of the ecosystem of considerable ecological importance, the perpetrator will be punished by imprisonment of at least 3 months, but not exceeding 5 years.[453] If the aforementioned dangers have been caused negligently, the punishment will be imprisonment of up to 5 years, *i.e.* the minimum threshold of 3 months imprisonment does not apply.[454] If not only the endangerment has been caused negligently, but also the placing on the market of unauthorized GM food was committed negligently, the imprisonment shall be at most 3 years.[455] The attempt to commit one of the criminal offences mentioned above will be punished as well.[456]

Breaches of the rules concerning requirements for the labelling of food free of GMOs as "ohne Gentechnik" are subject to imprisonment of up to 1 year or a fine.[457] In case of negligence, such breaches are considered administrative offences punished by a fine of up to 20,000 EUR.[458] The same applies if the label "ohne Gentechnik" is used without supporting documents.[459] The use of other labels than "ohne Gentechnik" is an administrative offence as well but punished by a fine of up to 50,000 EUR.[460] The same applies to violations of Regulation (EC) No. 1829/2003

[449] Art. 45(1), (2) Regulation (EC) No. 1829/2003; Art. 11 (1), (2) Regulation (EC) No. 1830/2003.
[450] Art. 4(2) Regulation (EC) No. 1829/2003.
[451] Sec. 6(1)(1) EGGenTDurchfG.
[452] Sec. 6(5) EGGenTDurchfG.
[453] Sec. 6(3)(1) EGGenTDurchfG.
[454] Sec. 6(6) EGGenTDurchfG.
[455] Sec. 6(7) EGGenTDurchfG.
[456] Sec. 6(4) EGGenTDurchfG.
[457] Sec. 6(3a) EGGenTDurchfG.
[458] Sec. 7(1), (7) EGGenTDurchfG.
[459] Sec. 7(6)(2)-(3), (7) EGGenTDurchfG.
[460] Sec. 7(6)(1), (7) EGGenTDurchfG.

and Regulation (EC) No. 1830/2003 concerning post-market monitoring, information, labelling and traceability requirements.[461]

As far as Directive 2001/18/EC applies, EU Member States have to "determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive".[462] Again, these penalties must be effective, proportionate and dissuasive.[463] Accordingly, the German GenTG lays down both criminal and administrative offences.[464]

Civil Liability

Civil liability in the field of genetic engineering is governed by the GenTG.[465] According to the GenTG, the operator has to pay damages caused by death, bodily injury, injury to health or damage to property which, in turn, are due to traits of an organism which were brought about by the use of genetic engineering.[466] Operator is any natural or legal person who uses genetic engineering (under conditions of containment), carries out deliberate releases of GMOs into the environment or places products containing or consisting of GMOs on the market at the very first marketing stage.[467] The operator's civil liability does not depend on fault. Thus, civil liability under the GenTG constitutes strict liability. The maximum amount of damages to be paid by the operator is 85 million EUR.[468] A compulsory cover does still not exist even though a statutory instrument may be adopted on the basis of the GenTG prescribing financial precautions in order to cover damages.[469] Concerning causality, the GenTG stipulates a rebuttable presumption: If the damage has been caused by GMOs it is presumed that the damage was caused by such traits of those organisms which were brought about by the use of genetic engineering.[470] The presumption is rebutted if it is likely that the damage is due to other traits of the organisms.[471] In addition, if facts suggest that personal injury or damage to property results from the use of genetic engineering, the operator, on request by the victim, has to provide information on the nature and process of the use of genetic engineering as far as such information is necessary for the purpose of ascertaining whether the operator is liable under the GenTG.[472]

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[461] Cf. 7(2), (3), (7) EGGenTDurchfG.

[462] Art. 33(1) Directive 2001/18/EC.

[463] Art. 33(2) Directive 2001/18/EC.

[464] Sec. 38, 39 GenTG.

[465] Sec. 32 et seq. GenTG.

[466] Sec. 32(1) GenTG.

[467] Sec. 3(7) GenTG.

[468] Sec. 33(1) GenTG.

[469] See Sec. 35 GenTG.

[470] Sec. 34(1) GenTG.

[471] Sec. 34(2) GenTG.

[472] See Sec. 35 GenTG.

All these rules on strict liability of the operator do, however, not apply if the placing on the market of a product containing or consisting of GMOs has been duly authorized.[473] Thus, in cases of death or bodily injury or injury to health (and only in such cases), general product liability law applies.[474]

In addition the rules on civil liability of the GenTG do not affect other provisions on civil liability.[475] Thus, *e.g.*, the 'Bürgerliches Gesetzbuch' (BGB), *i.e.* the Civil Code, is applicable as well which provides, *inter alia*, that the owner of real property may claim appropriate compensation if he or she has to tolerate immissions from neighbouring real property.[476] Civil liability according to this specific rule is independent of fault, and, thus, constitutes strict liability. What is more, this rule has been complemented, or rather concretized, by a special provision in the GenTG for the purposes of coexistence of GM, conventional and organic agriculture.[477] In accordance with this liability framework, GM farmers have to compensate conventional or organic farmers if the latter are prohibited from placing their products on the market[478] or if they have to label their products indicating the presence of GM material[479] or if they are prevented from using a label which could have been affixed to their products according to the rules related to their method of production[480] because of GM immissions.[481] The recovery of damages requires that the GM immissions occurred despite the fact that the GM farmer has complied with the standards of good professional practice.[482]

Product Liability

Product liability in the context of the use of GMOs is covered by the Law on Product Liability (Produkthaftungsgesetz – ProdHaftG),[483] *i.e.* the law on liability for defective products. The ProdHaftG's scope of application extends to GM products includ-

[473] Sec. 37(2) GenTG.

[474] See Sec. 37(1)(1) in connection with Sec. 37(1) GenTG and Jürgen Kohler, in: Staudinger, BGB, 2010, § 32 GenTG, para. 47.

[475] Sec. 37(3) GenTG.

[476] Cf. Sec. 906(2)(2) BGB.

[477] See Sec. 36a GenTG. In detail see, e.g., Hans-Georg Dederer, Die Nutzung der Gentechnik, in: Reinhard Hendler/Peter Marburger/Peter Reiff/Meinhard Schröder (eds.), Landwirtschaft und Umweltschutz, 2007 (UTR vol. 92), p. 222 et seq.; Jürgen Kohler, Schadensausgleich in Fällen des §36a Gentechnikgesetz, Natur und Recht 2005, p. 566; Gerhard Wagner, Nachbarhaftung für gentechnische Immissionen, Versicherungsrecht 2007, p. 1017.

[478] E.g., because of the presence of GM material from GMOs the placing on the market of which has not been authorized so far.

[479] E.g., because the traces of GM material exceed the 0.9 %-threshold.

[480] E.g., because the product may not be labeled, e.g., 'bio' or 'organic' as the presence of GM material exceeds the 0.9 %-threshold.

[481] See Sec. 36a(1), (3) GenTG.

[482] See Sec. 36a(2) GenTG.

[483] Gesetz über die Haftung für fehlerhafte Produkte (BGBl. 1989 I p. 2189), last amended by law of 19 July 2002 (BGBl. 2002 I p. 2674).

ing agricultural GM products.[484] However, the GenTG modifies product liability under the ProdHaftG to a certain extent. In fact, it is argued that only manufacturers who are holders of a marketing authorisation can be held liable for faulty GM products.[485] Accordingly, GM farmers would not be subject to civil liability under the ProdHaftG because it is typically not the GM farmer but the seed company having developed the transformation event which is the authorisation-holder. This is actually in line with the legislature's express original intent.[486] Nevertheless, the wording of the GenTG[487] is not that clear. In any case, manufacturers of GM products can be held liable even if the product's defect could not be diagnosed by the state of science and technology at the time when the product was placed on the market.[488]

Civil liability under the ProdHaftG is liability without fault, *i.e.* strict liability. According to the ProdHaftG, the manufacturer is obliged to pay damages resulting from death, bodily injury, injury to health or damage to property which is caused by the defect of a product.[489] Concerning the product defect, the damage and the causal relationship between the defect and the damage, the claimant bears the burden of proof. Liability of the manufacturer is excluded if the defect is due to the fact that the product complied with compulsory legal rules concerning the product's placing on the market at the time the product was placed on the market.[490] It is alleged, however, that this exemption from product liability does not apply to market authorisations because these administrative decisions did not constitute 'rules'.[491]

Summary

In Germany, field trials with GM plants and the placing on the market of GM food has come to a complete halt. This '*blocus total*' was brought about by the German public's highly critical attitude towards 'green genetic engineering' in general and GM food in particular as well as by the Federal Government's scientifically unwarranted suspension of the market authorisation for the Bt maize variety MON810. In addition, due to the strict liability provisions enacted in 2004, the German Farmers' Association advises every farmer against GM crop cultivation.[492] Meanwhile, as a

[484] Jürgen Kohler, in: Staudinger, BGB, 2010, § 37 GenTG, para. 14.

[485] See Sec. 37(2)(2) GenTG and Jürgen Kohler, in: Staudinger, BGB, 2010, § 32 GenTG, para. 50; Gerhard Wagner, in: Münchener Kommentar zum BGB, 6th ed., 2013, § 4 ProdHaftG, para. 16.

[486] BT-Drs. 11/5622, p. 37.

[487] See Sec. 37(2)(2) GenTG.

[488] Sec. 37(2)(2) GenTG.

[489] Sec. 1(1) ProdHaftG.

[490] Sec. 1(2)(4) ProdHaftG.

[491] Gerhard Wagner, in: Münchener Kommentar zum BGB, 6th ed., 2013, § 1 ProdHaftG, para. 43.

[492] http://media.repro-mayr.de/75/543375.pdf

consequence, biotechnology companies like Monsanto[493] or BASF Plant Science[494] have turned their back on Germany and Europe.

Thus, the amendments to the EU's legal framework for GMOs and, in particular, for GM food and feed in 2001/2003 did not achieve one of their main objectives, namely to overcome the Europeans' distrust vis-a-vis agricultural biotechnology and GM food by setting up a revised legal regime hailed one of the strictest GMO regimes in the world.[495] In fact, the market authorization procedure for GM food is highly politicized and its outcome, therefore, unpredictable, not to mention the intolerable duration of the authorisation process. Moreover, with regard to the public's deeply rooted scepticism vis-à-vis GM food, the compulsory GM specific labelling of GM food functions as an alarm signal provoking a chilling effect on consumers and their choice. GM specific labelling does not convey any meaningful positive connotations because no rational consumer would buy food simply or primarily because it is genetically modified.

Whether agro genetic engineering will play an important or even decisive role in ensuring food security is a highly controversial issue. In any case, the foreseeable adverse effects of climate change will confront agriculture with serious challenges. It should go without saying that genetic engineering ought to be considered an indispensable breeding technique among others for the purpose of developing, *e.g.*, drought or pest resistant crops. From this point of view, it is quite puzzling that both the EU and the German legal framework for 'green genetic engineering' in general and GM foods in particular are preoccupied with utmost precaution against health and environmental risks arising from GMOs whereas the humanitarian potentials of genetic engineering, especially regarding food security, are faded out.[496]

This does not mean that Germany and the other EU Member States do not live up to their various international human rights obligations according to which States have the duty to ensure food security because they enjoy a wide margin of appreciation concerning the means to be employed in order to conform to their duty. Although some doubt has to be cast on whether the labelling requirements comply with WTO law,[497] the EU's and Germany's current legal framework concerning the authorization of GM food may be considered by and large in conformity with GATT, the SPS Agreement and the TBT Agreement. It is rather the prohibitive

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[493] Cf. http://www.faz.net/aktuell/wirtschaft/unternehmen/genpflanzen-monsanto-verabschiedet-sich-von-europa-als-markt-12203300.html

[494] See BASF, Presse-Information of 16 January 2012: BASF konzentriert Pflanzenbiotechnologie-Aktivitäten auf Hauptmärkte in Nord- und Südamerika (http://www.basf.com/group/corporate/de/function/conversions:/publish/content/news-and-media-relations/news-releases/downloads/2012/P109d-Pflanzenbiotechnologie.pdf).

[495] European Commission (ed.), EU policy on biotechnology, 2006, p. 6, 8.

[496] Sec. 1(3) GenTG refers only to the "advancement of the scientific, technical and economic potentials of genetic engineering".

[497] See, e.g., Hans-Georg Dederer, Neues von der Gentechnik, Zeitschrift für das gesamte Lebensmittelrecht 2005, p. 307, at 326 et seq.

application of GM food law, e.*g.*, the scientifically unjustified delay in granting authorisations and the politically motivated, but scientifically unwarranted adoption of safeguard measures, which might be successfully challenged before a WTO Panel. Apart from that one may seriously doubt whether the current rather cumbersome, inflexible and clouded rules pertaining to GM food are, from a practical viewpoint, compatible with global trade flows of agricultural commodities taking into account that cultivation of GM crop is on the rise across the globe.

Chapter 3
Policies and Regulations in Belgium with Regard to Genetic Technology and Food Security: Country Report – Belgium

Luc Lavrysen, Frank Maes, and Piet van der Meer

The Belgian regulations for GMOs are to a large extent dictated by the EU regulatory framework for GMOs. The implementation of the relevant European Directives concerning GMOs and the application of the related Regulations is a mixed competence between the regions and the Federal Government. The implementation of Directive 2001/18/EC on the *deliberate release into the environment of genetically modified organisms*, is a task for the *federal authorities* in as far as it deals with the "placing on the market of genetically modified organisms as or in products within the Community". The regional authorities are involved as far as it deals also with "carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market". Regional competencies are e.g. involved in the authorisation of field experiments, because there may be risks to their environment and biodiversity. The implementation of Directive 2009/41/EC on *the contained use of genetically modified micro-organisms* is mainly a competence of the regions, because the laboratories in which these activities take place are seen as so-called "classified installations" that require a regional environmental permit. The decisions made by different administrative bodies are based on a common scientific evaluation system comprising the Biosafety Advisory Council (BAC) and the Biosafety and Biotechnology Unit (SBB), based on the Cooperation

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Agreement of 25 April 1997 between the Federal State and the Regions on the administrative and scientific coordination concerning biosafety.

The application of Regulation (EC) N° 1829/2003 on *genetically modified foods and feeds* is a federal competence. The same is true for Regulation (EC) N° 1830/2003 concerning *the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced* from genetically modified organisms.

The regulatory situation for GMOs in the EU and Belgium knows some complexities. As of the second half of the 1990s, the part of the regulatory system addressing placing the market of GMO products, started to stagnate, and consequently the EU Member States and Institutions have revised the regulatory framework in various steps. Despite these and other revisions, there is still much ongoing debate between the Member States and the EU institutions to further revise the regulatory framework, and the debate itself indicates that very few – if any – of the of the involved parties is content with the current system.

An often heard comment is that the EU regulatory system for GMOs is 'dysfunctional', whereby reference is made to the discrepancy between the significant R&D investments by the EU Member States and Institutions and the fact that there are so few realisations of that research, in particular in the field of agricultural biotechnology. Another discrepancy that is often referred to is that while many millions of tons of GM crops cultivated outside the EU are approved and imported for food and feed use in the EU, while European farmers are not allowed to grow those same GM crops. Clearly, one of the main reasons for the current situation is that the policies of some governments and politicians are not the same as they were in the time when the regulatory framework was designed, when the focus was on the environment, human health, research and the internal market. For some governments and politicians, other aspects have come into focus, such as societal debates and preferences for certain forms of agriculture. The so called 'nationalisation' proposal, has received a great variety of reactions, ranging from some Governments welcoming the proposal, to criticism that the proposal would go against the Internal Market and the WTO, and that it would affect the predictability of the system.

General Information[1]

Use of GMO in Food Production

Imported GMOs are generally used to make compound feed stuffs that are fed to livestock. About 80 % of compound feed stuffs contain GMOs.[2] There is currently no cultivation of GMOs in Belgium, mainly because there are no GM crops approved

[1] See on the general political and societal background of GMO regulation in Belgium: N. SCHIFFINO & F. VARONE, *Régulation publique des biotechnologies. Biomédecine et OGM agroalimentaires en Belgique et en France*, Gent, Academia Press, 2005, xii + 299 pp.

[2] Data BEMEFA.

for cultivation that are relevant for Belgian agriculture. The different regions in Belgium have a different approach to the use of GMOs in agriculture. The Walloon and Brussels-Capital Region have implemented co-existence regulations that are meant to discourage the cultivation of GM crops.[3] In their vision, the use of GM crops is not compatible with the agriculture that they wish to promote.[4] In the Flemish region a different approach is taken. The Flemish government does not stimulate the use of GM crops, but is of the opinion that GM crops that are proven to be safe and have a market authorization should be available for farmers to allow a free choice. The co-existence legislation in Flanders neither encourages nor discourages the use of GM crops, but is built to enable that freedom of choice.

Overall, the public opinion in Belgium about the use of GMOs in food production is not negative, be it that in the Walloon Region it may be less positive than in the Flemish Region. A survey held by EOS magazine and a recent survey among students of Ghent University showed a rather positive attitude towards the use of certain GMOs in food production. There is however also a strong minority opinion against GMOs that attracts quite some attention.

Food Security

There is no legal definition of food/feed security in Belgium, but in a White Book about Agriculture Research in Flanders, the crisis in food security is mentioned as one of the important external developments that need to shape agricultural research.[5]

Outline of the Regulatory Framework Relevant to Biosafety

Environmental policy in Belgium falls largely within the remit of the three autonomous regions: the Flemish Region, the Walloon Region and the Brussels-Capital Region. This is particularly the case for *environmental protection* and *nature conservation* (Art. 6(1), III, of the Special Act of 8 August 1980 on institutional reform (further: SAIR))[6] and, to a large extent, for *agricultural policy.* However, in some areas relevant to the subject matter dealt with, the federal authority is competent. Pursuant to the first point of the second paragraph of Article 6(1) SAIR, the federal Government is responsible for drawing up *product standards*. Product standards are defined as "*standards that establish the degree of pollution or nuisance which may not be exceeded in the composition or during the emission of a product, or which include specifications concerning product characteristics, methods of use, sampling*

[3] http://environnement.wallonie.be/legis/agriculture/qualite/qualite062.htm

[4] http://www.apaqw.be/

[5] http://www.vlaanderen.be/nl/publicaties/detail/witboek-landbouwonderzoek

[6] E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *Milieuzakboekje 2014*, Wolters Kluwer Belgium, Mechelen, p. 20–27.

standards, packaging, marking and labelling". A product standard is applicable *when the product is placed on the market*, *inter alia*, at the time of its introduction, importation or possession, for the purpose of sale or making available to a third party, offer for sale, offer for rent, rent etc.[7] Requirements relating to environmental protection that apply *after* the product has been placed on the market, such as those concerning the use or release of products, come under the power of the Regions and not of the federal authorities.[8] In the same sense the federal authority is competent *to set standards* (and control them) concerning *the quality of primary materials used in agriculture and products derived from plants* with a view to ensure food safety during the complete production chain (Art. 6 (1) V SAIR).

GMO Regulation

As with all EU countries, the regulations for GMOs are to a large extent dictated by the EU regulatory framework for GMOs.

The implementation of the relevant European Directives concerning GMOs and the application of the related Regulations in Belgium is a mixed competence between the regions and the Federal Government.

The implementation of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the *deliberate release into the environment of genetically modified organisms*, and repealing Council Directive 90/220/EEC,[9] is a task for the *federal authorities* in as far as it deals with the "placing on the market of genetically modified organisms as or in products within the Community" (Art. 1, second indent). The regional authorities are involved as far as it deals also with "carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market" (Art. 5–11). Regional competencies are e.g. involved in the authorisation of field experiments, because there may be risks to their environment and biodiversity.

The implementation of Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the *contained use of genetically modified micro-organisms* is mainly a competence of the regions, because the laboratories in which these activities take place are seen as so-called "classified installations" that require a regional environmental permit. Indeed, the Regions are competent with regard to what is described in the SAIR as: *"the policing of dangerous, unhealthy and noxious establishments, subject to measures of internal policy concerning worker protection."* This means that the Regions are competent for the environmental supervision of potentially noxious installations, for example, by a system of notifications and licence requirements, and in some cases more modern instruments, such

[7] D. MISONNE et al., *Legal constraints on national measures to promote environment-friendly products*, Brussels, Belgian Science Policy, 2004, p. 13.

[8] *Ibid*., p. 14.

[9] W. XIANG, *Risk Governance of GMOs in the EU and China*, Dissertation, Ghent University, 2013, p. 118–121.

as environmental impact assessment and safety reports. This competence comprises both preventive supervision (licences, standards) and curative supervision (e.g., safety measures).

The decisions made by different administrative bodies are based on a common scientific evaluation system comprising the Biosafety Advisory Council (BAC) and the Biosafety and Biotechnology Unit (SBB). The BAC must be consulted for the deliberate release of GMOs in the environment and the placing on the market of all GMOs and GMOs-based products; the SBB on contained use activities with GMOs and pathogens. The Council can be consulted by the Regions or the SBB for contained use activities. More information is available on the website of the Biosafety Advisory Council.[10]

Federal competencies are involved as well, however, as Article 13 deals with emergency plans for such premises. Federal government is competent with regard to civil protection and this comprises, *inter alia*, plans for dealing with disasters, and a coordinated action of the emergency services in the event of environmental disasters.

The application of Regulation (EC) N° 1829/2003 of the European Parliament and of the Council of 22 September 2003 on *genetically modified foods and feeds*[11] is a federal competence. The same is true for Regulation (EC) N° 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the *traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms* and amending Directive 2001/18/EC, and Regulation (EC) N° 1946/2003 of the European Parliament and of the Council of 15 July 2003 on *transboundary movements of genetically modified organisms*.

Given this historically grown division of competencies it is obvious that it was impossible in Belgium to regulate the whole issue in one piece of legislation applicable for the whole country. The solution that was chosen is a combination of a cooperation agreement between federal and regional authorities, on the one hand, and federal and regional acts and regulations on the other.

The relevant legal framework in Belgium is essentially constituted by[12]:

The *Cooperation Agreement* of 25 April 1997 between the Federal State and the Regions on the *administrative and scientific coordination concerning biosafety*. This cooperation agreement concerns not only GMOs and GMMs, but also organisms that are human pathogens. The Cooperation Agreement establishes a common scientific evaluation system for all biosafety-related matters. It is composed of the *Biosafety Advisory Council*,[13] which is charged with the task of evaluating the biosafety of activities or products for which GMMs, GMOs or parts thereof are used

[10] http://www.bio-council.be/

[11] W. XIANG, *op. cit.*, p. 121–125.

[12] More information can be found on the following website: http://www.biosafety.be/

[13] Royal Decree of 2 September 2005 appointing the members of the Biosafety Advisory Council, *Belgian Official Journal*, 6 October 2005. The Council is composed of 12 active and 12 deputy members. Half the members represent the various relevant federal and regional ministers, the other

and of the contained use of human pathogenic micro-organisms, and with offering advice in the context of the Cooperation Agreement. The secretariat of the Council is assumed by the *Service of Biosafety and Biotechnology (SBB)* of the Scientific Institute of Public Health (WIV-ISP). The SBB is composed of an administrative secretariat, and a multidisciplinary group of scientists.

The *Royal Decree* of 21 February 2005 regulating the *deliberate release into the environment and placing on the market of genetically modified organisms as or in products.*[14] This Royal Decree transposes Directive 2001/18/EC (territory covered: the whole of Belgium). This Royal Decree was adopted with some delay.[15] This delay was mainly due to disagreement on the way in which the Directive was to be transposed into Belgian law. The Minister of Consumer Affairs, Public Health and the Environment of the Green Party, had framed a preliminary draft which in some respects went further than what was prescribed by the Directive. One of the controversial points was that for each individual application to authorize field experiments, an assessment also had to be made of the *ethical aspects*[16] besides the required health environmental risk assessment. The government at the time was unable to reach an agreement on that point. The following government, without the Green parties, subsequently decided to drop this part and published the Royal Decree of 21 February 2005. A Royal Decree of 3 August 2007[17] transposes, as the deliberate release into the environment, the transport and placing on the market of genetically modified organisms is concerned, the relevant provisions of Directive 2004/25/EC on *environmental liability with regard to the prevention and remedying of environmental damage.*[18]

The following *Regional legislation on the contained use of GMOs and pathogens* have been adopted:

– *Flemish Region*: Decree of 28 June 1985 on environmental licences (in particular Articles 19c and 22b); Regulation of the Flemish Government of 6 February 1991 establishing the Flemish Regulations governing environmental licences (VLAREM I) (in particular Articles 1, 30°, 57b to 57i and Section 51 of Annex 1 and Annexes 15, 16 and 17); Regulation of the Flemish Government of 1 June

half are representatives of the scientific communities. For more info, see http://www.bio-council.be/

[14] *Belgian Official Journal*, 24 February 2005.

[15] Belgium has in fact been condemned by the European Court of Justice for delays in the transposition of the Directive into domestic law: ECJ, C-417/30, 30 September 2004, *Commission v. Belgium.*

[16] The Federal Council for Sustainable Development, a multi-stakeholder advisory council, was also divided on this issue. While the representatives of environmental groups and development cooperation organizations, consumer organizations, trade unions and some representatives of the scientific community supported the idea, a case-by-case ethical assessment was dismissed by the representatives of the employers' organizations. See: Federal Council for Sustainable Development, Opinion of 15 October 2002, www.frdo.be

[17] *Belgian Official Journal*, 20 September 2007.

[18] E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *op. cit.*, p. 834–836.

1995 on general and sectorial provisions relating to environmental safety (VLAREM II) (in particular Chapter 5.51 and Annexes 5.51.3–5.51.5);
– *Walloon Region:* Decree of 11 March 1999 on environmental licences; Walloon Government Regulation of 4 July 2002 establishing the sectorial and integral conditions for the contained use of genetically modified or pathogenic organisms;
– *Brussels-Capital Region*: Ordinance of 5 June 1997 on environmental licences; Regulation of 8 November 2001 of the Brussels-Capital Government on the contained use of genetically modified and/or pathogenic organisms and on the classification of the installations concerned.

(d) We should also mention the Act of 28 April 2005 amending the Act of 28 March 1984 on patents as regards *the patentability of biotechnological inventions*, which transposes Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions into Belgian law.

Regulatory Mechanisms

Various regulatory mechanisms apply, depending on the application:

- Contained use of GMOs
- Deliberate release of GMOs into the environment – placing on the market for cultivation
- GMOs in Food and Feed

Contained Use of GMOs

As mentioned before, in the three regions the contained use of GMOs is subject to the respective (regional) *environmental notification and permit systems*. In Belgium there are over 400 facilities that are approved for contained use with GMOs and/or pathogens.

In the Flemish Region e.g. *establishments* in which organisms are genetically modified or where such organisms are grown, stored, transported, destroyed, discarded or otherwise used need an environmental permit or notification. Depending on de risk level of the activities concerned, they need prior notification with the municipal government (risk level 1) or a permit of the provincial government (risk levels 2–4). Apart from that, for *each new contained use* of GMOs a prior notification and in some cases a consent is needed on the basis of a public notification dossier and a technical dossier, containing a risk analysis that will be assessed by the *Biosafety and Biotechnology Unit (SBB)* of the Scientific Institute of Public Health (WIV-ISP). The content of the dossiers varies according to the safety level of the

planned contained use. SBB will deliver an opinion to the competent authority, being the Environmental Permitting Division of the Department for the Environment, Nature and Energy of the Flemish Region that will decide on the application. The contained use can start the day after the consent is delivered or notification has been done, depending on the risk level of the contained use. The competent authority will determine, according the risk level, the general and specific containment and protection measures on the basis of the ALARA-Principle. The approach is based on Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms. A General Regulation of the Flemish Government (Chapter 5.51 VLAREM II) determines the general conditions under which the activities can take place.[19]

Similar procedures apply in the Walloon Region and the Brussels Capital Region.[20]

Safety of workers is regulated on the federal level by the Royal Decree of August 4, 1996 concerning the protection of works from risks related to exposure to biological agents at work, as amended several times. It implements Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work. It is also based on risk assessment and four different risk levels.

Deliberate Release into the Environment and Placing on the Market of GMOs

Legal Framework

The deliberate release of GMOs into the environment and the marketing of GMOs and products that contain GMOs, has been regulated on the *federal level*, based on the articles 132–132d of the Federal Act of 20 July 1991, by the Royal Decree of 21 February 2005 regulating the *deliberate release into the environment and placing on the market of genetically modified organisms as or in products.*[21] This Royal Decree transposes Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the *deliberate release into the environment of genetically modified organisms*, as well as Council Decision 2002/812/EC of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of

[19] E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *op. cit.*, p. 836–841.

[20] http://www.biosafety.be/CU/EN/ProceduresRWEN.html and http://www.biosafety.be/CU/EN/ProceduresRBEN.html

[21] The applications for approval are subject to administrative fees: Art. 5 of the Royal Decree of 13 November 2011. The Royal Decree has for its legal basis Articles 132a – 132d of the Act of 20 July 1991, which contains also the provisions concerning supervision and penalties: E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *op. cit.*, p. 831 and 835.

genetically modified organisms as or in products and Council Decision 2002/813/EC of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market.

Precautionary Principle

As the Directive (Article 1), the Royal Decree of 21 February 2005 (Article 1) provides that the objective of the Decree is, "in accordance with the *precautionary principle*", to protect human health and the environment when carrying out the activities covered by the Directive and the Decree.[22] Both the deliberate release of GMOs and placing on the market of GMOs as or in products are subject to the prior written authorization of the competent federal ministers (Articles 3 and 4). In order to obtain such authorization, a notification must be submitted along with a health and environmental risk assessment of which the requirements in terms of content are specified in Annex II. That same Annex also makes reference to the *precautionary principle*. In his risk assessment, the notifier must ensure that an accurate assessment is made on a case-by-case basis of the potential adverse effects on human health and the environment, which may occur directly or indirectly. This assessment must be conducted according to the nature of the organism introduced, the intended use and the receiving environment. Annex III imposes more specific requirements in this connection.

Notification and Assessment

In the standard procedure under the Royal Decree of 21 February 2005,[23] the notification dossier must be submitted to the *Federal Department of Health, Food Chain Safety and Environment.*[24] This authority investigates, together with the *Biosafety*

[22] In its opinion, the Federal Council for Sustainable Development had pointed out that the provisions in the preliminary draft Royal Decree should specify more accurately in which cases the precautionary principle applies. According to the Federal Council, once every possible kind of harm and the probability of such harm have been identified, the resulting situation allows a conventional risk assessment. This situation does not fall within the scope of the precautionary principle. The conditions for the risk assessment are therefore applicable. On the other hand, the precautionary principle applies in cases that are characterized by scientific uncertainty (or ignorance). In those cases, (any provisional) scientific knowledge is inadequate to determine every possible risk of serious or irreparable harm or damage.

[23] Articles 15–18 of Directive 2001/18/EC and the Royal Decree of 21 February 2005; in addition, there are also so-called differentiated procedures for special cases (e.g. GMOs that meet the criteria of Annex V and with which sufficient experience has been gained in the context of release into certain ecosystems).

[24] More particularly: Federal Public Service (FPS) Health, Food Chain Security and Environment - *Service Denrées alimentaires, Aliments pour Animaux et Autres Produits de Consommation* (http://www.biosafety.be/gmcropff/EN/CADREN.html).

and Biotechnology Unit (SBB), the admissibility of the dossier within 15 days after receipt thereof. If the dossier is found admissible, a European identification number is assigned and a copy of the dossier is sent to each of the *competent ministers of the region where the deliberate release will be conducted* and to the *Biosafety Advisory Council*. At the same moment also a public consultation starts that lasts for a month. Both the deliberate release of GMOs and placing on the market of GMOs as or in products are subject prior to the written authorization of the competent federal ministers (Articles 3 and 4). In order to obtain such authorization, a notification must be submitted along with a health and environmental risk assessment of which the requirements in terms of content are specified in Annex II.

In case of a notification for a field trial, the *Biosafety Advisory Council* delivers an opinion within 65 days; this opinion is communicated to the competent authority and the relevant regional minister(s). Where appropriate, the Biosafety Advisory Council, in delivering its opinion takes into consideration comments of the other Member States, and relevant comments by the public. The competent authority subsequently submits a decision to the relevant federal Ministers, who decide in agreement with the territorially competent regional Minister.[25] The competent regional Minister has a veto-right and can block the authorization of the release. The Ministers or their representatives adopt a reasoned decision within 90 days following the admissibility decision of the notification. This decision may consist in authorizing the release, subject to the conditions under which such release may take place; the authorization decision lays down at least the conditions put forward by the territorially competent regional minister. If the proposed release does not comply with the conditions stipulated by the Royal Decree of 21 February 2005, the application for authorization will be refused.

Monitoring

The notification comprises a technical dossier which must contain a *monitoring plan* in accordance with the applicable parts of Annex III in order to identify the effects of the GMO or GMOs on human health and the environment. It also comprises the *planned self-monitoring measures*, information concerning the monitoring, the remediation measures, waste processing and the planned emergency measures. Annex III to the Royal Decree imposes more specific requirements in this connection. Supervision of compliance with the conditions of authorization is entrusted to the *Directorate-General for the Protection of Public Health: Medicines* for medical GMOs and to the service of the *Federal Department of Health, Food Chain Safety and Environment* designated by the Minister for the other GMOs. The Minister ensures that emergency measures are taken if a serious risk occurs, such as suspending or terminating the placing on the market, and notifies the general public

[25] This agreement is deemed to have been given if the territorially competent regional Minister has not communicated any written objection to the authorization to the competent authority within ten working days after receipt of the opinion of the Biosafety Advisory Council.

through the internet site. Before taking such a decision, the Minister offers the authorization holder the opportunity to give his comments verbally or in writing, except in duly justified cases of extreme urgency. The competent authority notifies the Biosafety Advisory Council, the European Commission and the other Member States of the actions that have been taken and states the reasons for the decision.

New Information/Safeguard Clause

Article 42 of the Royal Decree contains the safeguard clause. This clause provides that if the competent federal Minister, on the basis of new or additional information which has become available after authorization has been granted and which may have an impact on the assessment of the health or environmental risks, or on the basis of the reassessment of the existing information in the light of new or additional scientific knowledge, has sufficient reason to assume that a GMO as a product or in products that has already been the subject of a proper notification dossier and of a written consent that was delivered in accordance with the Royal Decree or by virtue of a different licensing system of a Member State, poses a risk to human health or to the environment, the Minister may provisionally restrict or prohibit the use or sale of that GMO as a product or in products on "its territory" (this probably means the Belgian territory). The competent authority is responsible for the EU procedure intended to take a decision regarding a modification or withdrawal of the conditions of authorization. For this purpose it shall, where appropriate, request the opinion of the Biosafety Advisory Council (Art. 42).

Public Participation in Case of a Field Trial

The public is informed on a request for authorisation for deliberate release of a GMO, i.e. field trial, mainly through the official Internet sites (Art. 11), which forms part of the general site of the Federal Department of Health, Food Chain Safety and Environment. Within 5 days from the date of the letter confirming the admissibility of the notification, the competent authority organizes a consultation of the public. This consultation period lasts 30 days. During this period, the competent authority publishes the following information on the Internet site: the notification, except the confidential data; the summary of the notification and the information intended for the general public. In the case of clinical trials with human medicines, the publication on the Internet must not infringe privacy or medical secrecy. Other than in the case of clinical trials, the competent authority sends a copy of the notification, except the confidential data, to the mayor of the municipality or municipalities where a deliberate release is planned. Immediately upon receipt of this notification, the mayor informs the general public by posting a "notice of consultation" at the town hall. This notice remains posted for the whole duration of the public consultation. Throughout the consultation period, the notification, except the confidential data, is accessible to the public during the opening hours of the town hall and at least

once a week until 8 pm or on Saturday morning, in the place which the municipal authority has designated in the notice of consultation. The public can transmit its comments to the competent authority over the Internet site or by letter. Within 10 days following the public consultation, the competent authority informs the relevant federal Minister and the regional ministers of the observations made by the public and passes the observations in connection with biosafety on to the Biosafety Advisory Council (Art. 17). The Biosafety Advisory Council must investigate the comments by the public, and a summary is made of the public consultation as part of the decision report that is submitted to the competent Ministers (Art. 18(1)). Since the decision of the competent Ministers must be properly reasoned, it will also need to specify to what extent the comments of the public have been taken into consideration (Art. 18(3)). No later than 1 month after the decision, the following information is published on the Internet site: the opinions, decisions and amendments, and the reports of the competent authority and the supervisory office. The public can also consult the full notification, except the confidential data, by simple request to the competent authority (Art. 21). Article 43 provides that the Minister, the regional Ministers, the Supervisory Office, the Biosafety Advisory Council and the SBB must not divulge to third parties any confidential information that was notified or exchanged under the Royal Decree or Directive 2001/18/EC; they must also protect intellectual property rights relating to the data received. The notifier may indicate the information in the notification, the disclosure of which might harm his competitive position and which should therefore be treated as confidential. Verifiable justification must be given in such cases. It is the competent authority which, after consultation with the notifier, decides which information will be kept confidential, and informs the notifier and the competent regional ministers of its decision. Article 43(4) provides that in no case the following information may be kept confidential: general description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses; methods and plans for monitoring of the GMO or GMOs and for emergency response; health and environmental risk assessment and the opinions of the Biosafety Advisory Council. As was already said, confidential information will not be made public, but will form a separate attachment to the notification to which the competent authorities naturally do have access.

Public Participation in Case of Requests for Authorisation of the Placing on the Market of GMOs

The substance of the regulations dovetails on this point with what has been provided in Articles 12–24 of the Directive 2001/18/EC and the accompanying Annexes. The procedure involves public consultation. Article 32 provides that, in order to simplify the public consultation procedure organized by the European Commission, the competent authority should publish a summary of the notification on the Internet site as soon as the summary of the notification has been forwarded, along with information that is intended for the public. From the date of this publication, the public

has 30 days in which to present observations to the European Commission, and the full notification, except the confidential data, can be consulted by simple request to the competent authority. Within 5 days after receipt of the observations made by the public, the competent authority informs the Minister of the observations by the public and passes the observations in connection with biosafety on to the Biosafety Advisory Council for an opinion. In delivering its opinion, the Biosafety Advisory Council must take into account the relevant observations of the public (Art. 31(3)). The Biosafety Advisory Council must also take into consideration any observations made by the other Member States, in accordance with the procedures for exchange of information.

The relevant federal Ministers ultimately decide whether, and under which conditions, the Belgian Government agrees/disagrees in the EU voting procedure that the GMO in question may be placed on the market.

Judicial Review

The decision on the notification, the withdrawal of an authorization and a provisional restriction or a provisional ban in the context of the safeguard clause are administrative legal acts that can be challenged by an action for annulment and an action for suspension before the *Council of State*. The Council of State carries out a legality review. This review not only involves testing such individual decisions against higher legal standards (European law, Constitution, Statutes and Royal Decrees), but also against the formal obligation of justification and the principles of good government. Both substantive and formal aspects are concerned. Both natural and legal persons who can prove an interest can bring such an action within 60 days after they have been notified of the challenged decision. For the Council of State, the interest in question must be a personal, direct, positive and legitimate interest. There must always be an individualized connection between the applicant and the challenged legal act. The act in question must be prejudicial, in other words, it must cause a certain disadvantage to the person bringing the action. However, it can concern a minor material or even purely moral interest.[26] There is little doubt that the neighbouring residents or farmers of a test field have a sufficient interest. Public (e.g. municipal authority) or private legal entities (e.g. non-profit conservation organizations) can take action before the Council of State. In the latter case, it is examined whether the organization has the necessary authority to defend the collective interest which it has defined in its bylaws, in other words, whether it is sufficiently representative.[27] When the Council of State annuls a decision, the administrative procedure must be resumed and the administrative authority is bound by the judgment of the Council of State. Consequently, it will have to make sure that it does not commit the same breach again.

[26] E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *op. cit.*, p. 1274–1275.

[27] *Ibid.*, p. 1329–1330.

In the case of a manifest infringement or a serious risk of infringement of this legislation, an *action for suspension* may be brought before the President of the Court of First Instance. This can also be done by non-profit organizations which have been incorporated for at least 3 years and which can prove that there is an actual activity going on that corresponds to their corporate purpose and that this activity is connected with a collective environmental interest which they seek to protect. Individual citizens can indirectly also bring such an action, more particularly "on behalf of the municipality", in the event that the municipal authority refuses to institute such an action.[28]

Practical Experiences

An overview of concluded and ongoing procedures of notifications of activities with GMOs can be found on the website of the Belgian Biosafety Advisory Council.[29]

For concluded procedures, the website provides details and further links to, inter alia:

- Notifications for deliberate release of GMO's (GM plants and other) for any other purpose than for placing on the market
- Notifications for transgenic plants to be placed on the EU market under Directive 2001/18/EC – Part C
- Notifications submitted under Regulation (EC) N° 1829/2003 on genetically modified food and feed
- Notifications submitted under the Novel Food Regulation (EC) N° 258/97

There have been quite a number of notifications for deliberate release of GMOs in Belgium for purposes other than placing on the market. These concerned mainly field trials with GM plants and clinical trials with GMOs other than plants.

So far, only one authorization has been granted through Belgium for the placing on the market of GMOs, more particularly for the "commercial release of MS8, RF3 and MS8xRF3 oilseed rape", to Bayer Crop Science. The authorization has been given for import and processing for nutritional purposes; no authorization has been given for cultivation. The decision was delivered by the European Commission, because no qualified majority was reached at the Regulatory Committee and at the Council level.

[28] *Ibid.*, p. 1298–1300.

[29] http://www.bio-council.be/ongoing-dossiers/Pages/Ongoing-dossiers.aspx

Coexistence and GMO-Free Zones

In all the three regions general legal framework on *coexistence of genetic modified cultures with conventional and organic cultures* has been adopted in view of the implementation of article 26a of Directive 2001/18/EC (as amended by Directive 2008/27/EC).

The Decree of 3 April 2009 of the *Flemish Region*,[30] which is applicable to all cultures of GMOs in that region that would be authorised in the framework of Directive 2001/18/EC, aims to ensure the free choice of farmers between GMO, conventional and organic cultures and to avoid economic losses for conventional and organic cultures due to unintended presence of GMOs above the EU threshold value for labelling. It obliges farmers (and their contractors) who intend to cultivate GMOs to follow a specific training. They have to notify in advance the Flemish authorities and neighbouring farmers of that intention. These neighbouring farmers can object to the intended culture on the basis of a reasoned proper economic interest. The farmers who cultivate GMOs have to contribute to a Public Fund for compensation of economic losses. A Coexistence Commission, composed of representatives of various administrations and scientific experts, has to assess the objections from neighbouring farmers and the applications for compensation. All cultures of GMOs are registered in a public register. Unforeseen and abnormal events must be notified. On the basis of this Decree, the Flemish Government has adopted some general rules concerning coexistence,[31] as well as rules specific for maize, potatoes and sugar beet.[32]

In the *Walloon Region*, the Decree of 19 June 2008 addresses co-existence. The Executive Order of the Walloon Government, implementing the Decree,[33] provides for the possibility to establish *GMO-free zones*. Such a zone consists of arable land of at least 3 farmers and covering at least 150 ha. The concerned farmers may introduce a demand for the instauration of such a zone, and when approved, with limitations on GMO cultivation for adjacent land as a consequence.[34] Apart from that it

[30] *Belgian Official Journal*, 4 May 2009.

[31] B.Vl.Reg. van 15 oktober 2010 houdende de vaststelling van algemene maatregelen voor de coexistentie van genetisch gemodificeerde gewassen met conventionele gewassen en biologische gewassen, *BS* 30 November 2010.

[32] B.Vl.Reg. van 15 oktober 2010 houdende de vaststelling van specifieke maatregelen voor de coexistentie van genetisch gemodificeerde maïsgewassen met conventionele maïsgewassen en biologische maïsgewassen, *BS* 30 November 2010; B.Vl.Reg. van 10 November 2011 houdende de vaststelling van specifieke maatregelen voor de co-existentie van genetisch gemodificeerde aardappelgewassen met conventionele aardappelgewassen en biologische aardappelgewassen, *BS* 23 December 2011; B.Vl.Reg. van 10 November 2011 houdende de vaststelling van specifieke maatregelen voor de co-existentie van genetisch gemodificeerde suikerbieten met conventionele suikerbieten en biologische suikerbieten, *BS* 23 December 2011.

[33] A.G.w. du 7 mars 2009 relatif à la coexistence des cultures génétiquement modifiées avec les cultures conventionnelles et les cultures biologiques, *BS* 27 March 2009.

[34] Art. 30 and 31.

has been suggested that 124 municipalities and the Walloon Region have declared themselves GMO-free. Such declarations have no legal consequences.

A comparison between the various systems shows that the specific rules for crops are much more stringent in the Walloon region than in Flanders. For instance the isolation distance for GM maize is in Flanders 50 m, where in Wallonia it is 600 m, de facto making GM maize cultivation very virtually impossible. There is also a big difference in the intent with which the Flemish and Walloon coexistence legislation was written (see above). In the *Brussels Capital Region* any cultivation of genetic modified plants is simply forbidden.[35]

GMO in Food Production

Regulation (EC) No 1829/2003

This matter is regulated on the EU level by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on *genetically modified food and feed*. This Regulation provides the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market. It lays down EU procedures for the authorisation and supervision of genetically modified food and feed provisions for the labelling of genetically modified food and feed (Art. 1). Chapter II deals with the authorisation, supervision and labelling of genetically modified food, while chapter III does the same for genetically modified feed. Chapter IV contains common provisions for both applications.

Co-operation Between National and EU Bodies

The industrial operator can submit his application in accordance with this Regulation for all food products containing GMOs in compliance with the provisions provided for by Directive 2001/18/EC on the deliberate release of GMOs into the environment. The industrial operator can submit a single application for food and feed uses and for cultivation. This means that a GMO that has obtained authorisation can be used not only in food and animal feed but also for cultivation or deliberate release into the environment. Once the application has been made by an industrial operator, the receiving national authority concerned acknowledges receipt in writing within 14 days and informs the European Food Safety Authority (EFSA), which is responsible for risk assessment in the food sector. The latter has 6 months in which to conduct this assessment. The Commission is responsible for risk management. On

[35] Art. 5 of the Ordinance of 3 April 2014 concerning co-existence of GMO crops with conventional and organic cultivation, *BS* 13 May 2014.

the basis of the risk assessment carried out by the EFSA, the Commission draws up within 3 months a draft decision accepting or rejecting the application. It then submits this draft to the Standing Committee on the Food Chain and Animal Health. If this committee accepts the proposal, it is finally adopted by the Commission; if it does not, the proposal is assessed by an appeal committee (NB: In the new comitology procedure, the Council of Ministers is replaced by an appeal committee. The difference between the Standing committee and the appeal committee is that the first is populated with member state 'experts', where the second is populated with member state 'diplomats'.). If the latter does not reach a position within 3 months or if it is unable to reach a qualified majority for or against, the Commission may adopt its proposal. The marketing authorisation is given for a period of maximum 10 years and is renewable.

Enforcement

The Regulation is in Belgium enforced by the same authorities as those that intervene in the national procedures. The websites show the applications for authorization and the public consultations and inquiries under way by a link to the European website. The opinions of the Biosafety Advisory Council are published on its own website. So far, more than 50 opinions have been delivered with regard to EU applications.[36] Decisions of the European Commission fall outside the jurisdiction of the Belgian courts. Such decisions can only be challenged before the EU Courts (General Court or Court of Justice) under the conditions set out in Article 263(4) of the TFEU. As is known, the Court of Justice upholds in this matter a very strict interpretation of the criterion "of direct and individual concern". It has to be seen if under the new additional criterion "a regulatory act which is of direct concern to them and does not entail implementing measures" Commission decisions such as resulting from the Regulation, can be challenged by interested parties. The matter can also arise before a national court of law. That Court must then of course refer the case to the European Court of Justice for a preliminary ruling on the validity of the decision of the European Commission (art. 267 TFEU).

Role of Belgian Biosafety Advisory Council

The Regulation provides that the EFSA may ask the appropriate food assessment body of a Member State or a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out assessments (Art. 6(3)(b) and (c)). In case the application covers cultivation, EFSA must consult a MS. Belgium has received a mandate from EFSA for the evaluation of four cultivation applications.

The national competent authority receives the applications for authorization and the EFSA informs the European Commission and the other Member States of the

[36] http://www.bio-council.be/

applications (Art. 5(2)(a) and (b)). Although the Regulation does not say so in so many words, the purpose of those applications could not be other than to allow the competent authorities to express their views on the matter during the course of the procedure, either in the form of an opinion to the EFSA, or through the public consultation procedure, or by taking part in the Committee referred to in Article 35. In practice, the Belgian Biosafety Advisory Council delivers an opinion. It is current practice that all member states' biosafety advisory bodies participate in commenting to a dossier, before the EFSA opinion is formed. EFSA consults the member states. This means that in Europe more than 200 people are actively involved in assessing a dossier. In Belgium the Biosafety Advisory Council provides a formal advice after the EFSA GMO panel has formulated its opinion.

Thresholds

A threshold value is referred to in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the *traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms*. This Regulation covers all products which consist of GMOs or which contain (processed) products from GMOs (this includes fields as diverse as the products, which are intended for entry into the human or animal food chain, products destined for industrial processing for uses other than consumption (e.g. in the production of biofuel) or even products destined to be used ornamentally (e.g. in the production of cut flowers)) and foodstuffs and animal feed products made from GMOs. All the products covered by this Regulation are subject to compulsory labelling, which shall enable consumers to be better informed and will offer them the freedom to choose to buy products consisting of, containing or made from GMOs. Traceability enables GMOs and their products to be traced throughout the production chain. This system is based on the transmission and holding of information by each operator. All food or feed products, including those intended directly for processing are subject to the labelling obligation when they consist, contain or are made from GMOs. *Only traces of approved GMOs are exempt from this obligation if the ingredients do not exceed the threshold of 0.9 % and if their presence is adventitious and technically unavoidable*. The Member States carry out measures for the inspection and monitoring of products, including sampling and quantitative and qualitative analyses of food and feed. These measures entail the Member States being able to withdraw from the market a product that does not meet the conditions laid down in this Regulation. So far, no additional laws or regulations have been adopted at the national level with a view to the implementation of Regulation 1830/2003. Inspection is carried out by the *Federal Agency for the Safety of the Food Chain.*

Implementation and Enforcement, Controlling Regime

Supervision of compliance with the conditions of authorizations is entrusted to the Directorate-General for the Protection of Public Health: Medicines for medical GMOs and to the service of the Federal Department of Health, Food Chain Safety and Environment designated by the Minister for the other GMOs. They have broad supervising powers, including the power to take safety measures (Art. 132a of the Act of 20 July 1991, as amended by the Act of 1 March 2007). The penalty provided for essentially consists of the right of the Minister to withdraw the consent. Such withdrawal can be resorted to if the conditions for obtaining the authorization are not or no longer satisfied, and no alternative settlement is arrived at between the holder of the authorization and the Minister or his representative, where appropriate after the opinion of the Biosafety Advisory Council has been sought. Authorization can also be withdrawn if incorrect or misleading information has been given, on the basis of which the authorization had been granted. Before withdrawing an authorization, the Minister offers the authorization holder the opportunity to give his comments verbally or in writing, except in duly justified cases of extreme urgency (Art. 24 of the Royal Decree of 25 February 2005). Violations can be penalized by the criminal court with 1 month's to 8 years' imprisonment and a fine of 6,000 euros to 60,000,000 euros or, in case of non-prosecution, by the administrative authority with an administrative fine of at least 6,000 euros and up to 30,000 euros (Art. 132c and 132d of the Act of 20 July 1991, as amended by the Act of 1 March 2007). Inspection of Regulations 1829/2003 and 1830/2003 is carried out by the Federal Agency for the Safety of the Food Chain.[37]

Labelling

Labelling Regime

Apart from the provisions laid down in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the *traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.* According to Art. 11 of that Regulation Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission, not later than 18 April 2004 and shall notify it without delay of any subsequent amendment affecting them. No specific national rules in this respect have been adopted. However general labelling requirements are laid down in

[37] http://www.afsca.be/home-en/

different Articles of the Royal Decree of 21 February 2005, and those provisions are subject to the sanction provisions of the Act of 20 July 1991 and the various sectorial Acts governing specific categories of goods, products or materials (Art. 49 of the Royal Decree).

Legislation Addressing Labelling Fraud

When the labelling requirements provided for by the Royal Decree of 21 February 2005 are not observed, the sanctions of the Act of 20 July 1991, provided for in Art. 132b, apply. The competent inspectors can also seize or confiscate GMOs and products containing GMOs that are not in conformity with the regulations (Art. 132a). Similar powers are given under the Act of 24 January 1977 protecting the health of consumers with regard to food stuff and other products and under the Act of 21 December 1998 concerning product standards promoting sustainable production and consumption patterns and protecting the environment, public health and the workers. Articles 10 and 11 of the Act of 6 April 2010 concerning market practices and consumer protection contain general provisions on labelling. It contains also a section on unfair commercial practices inspired by Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market.[38] A practice is misleading if it contains false or untrue information or is likely to deceive the consumer. Unfair commercial practices can be combatted trough an action for cessation. The articles 110–118 of the Act of 6 April 2010 organise a private enforcement remedy through injunctive relief. The range of parties entitled to institute proceedings for infringement of any provisions of the act is very broad: the parties concerned the Minister of Economic Affairs, the Director-General of DG Enforcement and Mediation, trade organisations and consumer organisations. The President of the Commercial Court may order the cessation or the prohibition of any breach of the Act. In addition, the President can order that the judgement or a corrective statement should be published. Art. 123 of The Act establish an administrative warning procedure. Warnings may be issued by the Minister or the officials designated by the Minister, requesting that the undertaking concerned cease the infringement. The infringer may undertake to cease the infringement, and, where appropriate, that undertaking may be published. If the infringer dies not obey, the Minister of Director-General may initiate legal action for a cease and desist order, a settlement can be made or criminal enforcement can be started.[39]

[38] B. KEIRSBILCK, *The New European Law of Unfair Commercial Practices and Competition Law*, Oxford and Portland, Hart Publishing, 2011, 702 p.

[39] B. KEIRSBILCK, *op. cit.*, 455–457.

Liability

Genetic Technology

As *civil liability* for damage against persons, goods or economic interests is concerned, there is no specific legislation on liability for GMO-related activities. The general fault based liability of Art. 1382 of the Civil Code is applicable. A breach of a statutory duty (including duties imposed by GMOs legislation) or the general duty of care qualifies as a fault. Compensation for personal injury, direct property damage and the ensuing economic losses, is possible, provided that a causal link can be proven between these damages and the fault.[40] Pure ecological damage is not covered. However, the Royal Decree of 21 February 2005 provides that the notification of a deliberate release for other purposes than placing on the market must contain a signed declaration of civil liability (Art. 13(1)(f)). This declaration reads: "*I, the undersigned notifier,…, hereby assume full civil liability for any damage caused to human and animal health, property or the environment as a result of the tests*". The scope of this clause is limited. It does not alter the common fault liability for damage that is based on Article 1382 of the Civil Code.[41] At most, it may cause the liability for damage to be channelled to the notifier.

As indicated above, in the Walloon and Flemish regional legislation on co-existence there is an obligation of farmers who cultivate GMOs to compensate the economic losses that may be caused to conventional or organic cultures, including the obligation to buy the harvest that cannot be placed on the market because of (involuntary) admixture. The GMO farmers have to pay a contribution to a Fund that will compensate for the economic losses.

As *liability under public law* is concerned, the federal and regional legislation, adopted in view of the implementation of Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on *environmental liability with regard to the prevention and remedying of environmental damage*, is relevant.[42] De federal legislation – the Royal Decree of 3 August 2007[43] – is applicable for environmental damage that is caused by the deliberate release into the environment, the

[40] B.A. KOCH, "General Report" in B.A. KOCH (ed.), *Liability and Compensation Schemes for Damage Resulting from the Presence of Genetically Modified Organisms in Non-GM Crops. Reports*, April 2007, 45–53, http://ec.europa.eu/agriculture/analysis/external/liability_gmo/full_text_en.pdf; V. WILCOX, "Summaries of the Country Reports" in B.A. KOCH, *op. cit.*, p. 129; B. DUBBUISSON & G. GATHEM, "Belgium" in B.A. KOCH (ed.), *Liability and Compensation Schemes for Damage Resulting from the Presence of Genetically Modified Organisms in Non-GM Crops. Annex I. Country Reports*, April 2007, p. 32–50, http://ec.europa.eu/agriculture/analysis/external/liability_gmo/annex1.pdf

[41] B. DUBBUISSON & G. GATHEM, *loc. cit.*, p. 33.

[42] B. DUBBUISSON & G. GATHEM, *loc. cit.*, p. 33; W. XIANG, *op. cit.*, p. 175–182.

[43] Royal Decree of 3 August 2007 concerning prevention and remedying of environmental damage due to the placing on the market of GMOs and products containing GMOs, *Belgian Official Journal*, 20 September 2007.

transport and placing on the market of GMOs. The regional legislation[44] is applicable when environmental damage is caused by any contained use, including transport, involving genetically modified micro-organisms. The purpose of the Environmental Liability Directive ("ELD"), and the Belgian legislation that transpose it, is to establish a so called 'administrative' framework of environmental liability, based on the "polluter-pays" principle, to prevent and remedy environmental damage, via a public law approach. The ELD aims at ensuring that the financial consequences of certain types of harm caused to the environment will be borne by the economic operator who caused this harm. The competent authorities shall ensure the effective implementation and enforcement of the ELD. They are for instance, in charge of specific tasks such as assessing the significance of the damage and determining which remedial measures should be taken (in co-operation with the liable operator). An operator is any natural or legal, private or public person who operates or controls the damaging occupational activity, including the holder of a permit or authorisation for such an activity or the person registering or notifying such an activity. However, due to the definition and the thresholds provided for in the definition of environmental damage, it is not likely that GMOs related activities will cause damage in the sense of the ELD.

Product Liability

The Act of 25 February 1991 on the liability for products with defects[45] implements directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. GMOs, including 'primary agricultural products',[46] and products containing them, can fall under the scope of this piece of legislation if damage is caused by product that is defective. A product is understood to be defective "*when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it*

[44] *Brussels Capital Region*: Ordinance of 13 November 2008 on environmental liability with regard to the prevention and remedying of environmental damage, *Belgian Official Journal*, 14 November 2008; *Flemish Region:* Decree of 21 December 2007 supplementing the Decree of 5 April 1995 containing general provisions concerning environmental policy with a Title VX Environmental Damage, transposing Directive 2004/35/EC, *Belgian Official Journal*, 12 February 2008; *Walloon Region*: Decree of 22 November 2007, amending Book I of the Environmental Code with regard to the prevention and remediation of environmental damage, *Belgian Official Journal*, 19 December 2007; E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *op. cit.*, 123–142.

[45] *Belgian Official Journal*, 22 March 1991.

[46] B. DUBBUISSON & G. GATHEM, *loc. cit.*, p. 40. The Belgian Act has not implemented the exception of *"primary agricultural products and game"* being *"the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing*" provided for in directive 85/374/EEC. The exception, provided initially in the Belgian Act, was deleted by the Act of 4 December 2000.

could reasonably be expected that the product would be put; (c) the time when the product was put into circulation".[47] The strict liability system – channelled to the producer and provided that none of the defences is applicable – covers only (a) damage caused by death or by personal injuries; (b) damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of 500 EUR, provided that the item of property: (i) is of a type ordinarily intended for private use or consumption, and (ii) was used by the injured person mainly for his own private use or consumption.[48]

Discussion

Returning to the overall topic of this report, "Policies and regulations with regard to genetic technology and food security", the authors make the following general observations.

As for all EU countries, regulation of genetic modification and of GMOs in Belgium is to a large extent shaped by the EU regulatory framework for GMOs.

The regulatory situation for GMOs in the EU knows some complexities:

- The EU regulatory framework entails Directives, Regulations, Decisions and Guidelines, each with their own objective, scope and legal basis (for example, Directive 2009/41/EC is an 'environmental protection' directive, whereas Directive 2001/18/EC is an 'internal market' directive);
- Some decisions within this framework are collective decisions, in which the Member States, EFSA and the European Commission play a role.
- The implementation on the national level, involves in many Member States various governmental levels, ranging from the national or federal level, via regional or provincial levels, to local levels. Belgium is a good example of this, whereby there is a division in competencies between the federal government and the regions.[49]

As of the second half of the 1990s, the part of the regulatory system addressing placing the market of GMO products, started to stagnate, and consequently the EU Member States and Institutions have revised the regulatory framework in various steps, such as:

- Directive 2001/18/EC – amendments of the original Directive on Release into the Environment

[47] A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation; B. DUBBUISSON & G. GATHEM, *loc. cit.*, p. 35.

[48] B.A. KOCH, *loc. cit.*, 55–56; V. WILCOX, *loc. cit.*, p. 130; B. DUBBUISSON & G. GATHEM, *loc. cit.*, p. 39–40.

[49] *Supra* § 1.3.

- Adoption of the Regulation (EC) N° 1829/2003 (genetically modified food and feed), and 1830/2003 (traceability and labelling)
- Adoption of Commission Implementing Regulation (EU) n° 503/2013 on applications for authorisation of genetically modified food and feed.

Despite these and other revisions, there is still much ongoing debate between the Member States and the EU institutions to further revise the regulatory framework, and the debate itself indicates that very few – if any – of the of the involved parties is content with the current system.

An often heard comment is that the EU regulatory system for GMOs is 'dysfunctional', whereby reference is made to the discrepancy between the significant R&D investments by the EU Member States and Institutions and the fact that there are so few realisations of that research, in particular in the field of agricultural biotechnology. Another discrepancy that is often referred to is that while many millions of tons of GM crops cultivated outside the EU are approved and imported for food and feed use in the EU, while European farmers are not allowed to grow those same GM crops.

Given the context of this report, i.e. the 19th International Congress of Comparative Law, the authors believe that it is appropriate to assess whether the regulatory framework itself can *a priori* not function properly, or that the regulatory framework is not implemented properly.

Following up on the above statement that the EU regulatory framework knows some complexities, a first question is whether the system is, also when compared to other systems, too complex.

When compared to regulatory frameworks for GMOs in other parts of the world, we note that complexity is not unique for the EU. Regulatory frameworks in other parts of the world know similar complexities. For example, the regulatory framework of the United States entails regulations from various Government agencies, such as the EPA, the USDA and the FDA, with each their own objective, scope and definitions.

When we compare the EU regulatory framework for GMOs with EU regulatory frameworks for other topics, then we note that overall there are similar complexities in terms of mixed regulatory tools, mixed competencies etc.

The main mechanism in the EU regulatory framework for GMOs is an authorisation system, in particular for field trials and placing on the market of GMOs and GMO products. As with other authorisation systems, the system for GMOs contains standard elements, such as: information requirements for requests/applications, rules for public involvement and confidentiality of data, time periods, procedures and criteria for decision making and the establishment of a capable scientific body, EFSA.

In summary: while neither claiming nor rejecting that the current regulatory framework for GMOs is the best way to regulate his new technology, the current system does contain the standard elements of an authorisation system, i.e. the sys-

tem can in principle function as it was designed.[50] In fact, the experiences from the early years of the regulatory system show that the system could and indeed did function as it was designed, i.e. allowing authorities to make informed decisions that involve key areas such as food security, human health and environment.

A next question is how the authorisation system is applied in practice, e.g. whether decisions are taken in accordance with the legal time limits, procedures and criteria.

As various surveys suggest,[51] for contained use and field trial applications, decisions are generally taken in accordance with the legal time limits, procedures and criteria.

Yet, with applications for placing on the market of GMOs and GMO products, the situation is quite different, e.g:

- For many applications for placing on the market, the legal time frames for decisions have been exceeded with many months and often with years.[52]
- For many applications the EU Commission has not submitted after the EFSA opinion within the legal time frame a draft decision for a vote by Member States. In a ruling of 26 September 2013,[53] the General Court confirmed that in doing so, the Commission had failed in its duties.
- Several Member States have invoked the 'safeguard clause', which allows the provisional prohibiting a GMO if there is new scientific information that suggests risk. Despite that EFSA has concluded that there was no valid scientific justification for these bans, these bans maintained.

As the above examples show, EU Member States and EU Institutions do not always comply with the regulatory system for GMOs that they themselves designed. This is disconcerting in itself, as it affects the 'Rule of Law', which touches on the question how citizens of the EU can be expected to always follow the rules, when Governments and EU institutions do not?

When we look for reasons behind the current situation, then we come to the second topic of this section: "policies".

Clearly, one of the main reasons for the current situation is that the policies of some governments and politicians are not the same as they were in the time when the regulatory framework was designed, when the focus was on the environment, human health, research and the internal market. For some governments and politi-

[50] When talking about 'functioning authorisation systems' the authors refer to systems whereby decisions are taken within the legal time limits, whereby decisions are taken on the basis of the criteria laid down in the regulations, while safeguarding basic requirements for public information and confidentiality.

[51] See for example http://www.cogem.net/index.cfm/nl/publicaties/publicatie/survey-on-the-implementation-of-directive-2009-41-ec

[52] See for example: http://www.europabio.org/positions/approvals-gm-crops-eu-january-2014-update

[53] Case T-164/10, *Pioneer Hi-Bred International vs the European Commission*.

cians, other aspects have come into focus, such as societal debates and preferences for certain forms of agriculture.

To accommodate for this, the European Commission has presented a proposal that would allow, after a GM crop is approved on grounds of safety, Member States to ban cultivation that GM crop in their territory, for reasons other than safety.

At EU level the European Parliament will indeed have end of 2014 – early 2015 a second reading on the controversial Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory. The Commission submitted that proposal to the Council on 14 July 2010. The aim of the proposal is to provide for a legal basis in order to authorise Member States to restrict or prohibit the cultivation, in all or part of their territory, of GMOs that have been authorised at EU level. Discussions on this legislative initiative were held within the Council and its preparatory bodies during various Presidencies. The outcome of these discussions showed that although a significant number of delegations broadly support the proposal, a blocking minority of delegations could not accept it. In July 2011 the European Parliament adopted a set of amendments at first reading. At its meeting on 9 March 2012, the Environment Council noted that no Political Agreement was possible to reach as a blocking minority of delegations continued to express misgivings on the proposed compromise text. Since then, successive Presidencies have noted that this blocking situation had remained. In February 2014, the General Affairs Council held a policy debate during which a significant number of Ministers favoured the revision of the EU legislation governing the authorisation of GMOs for cultivation. At its meeting on 3 March 2014, the Environment Council welcomed the re-examination of the Commission proposal on the basis of a revised text that had been prepared by the Presidency. At its meeting on 28 May 2014, the COREPER agreed, in principle, on the said Presidency's text and invited the Environment Council to adopt a Political Agreement at its meeting on 12 June 2014.[54] The draft takes the form of a proposal for a Directive, based on art. 114 TFEU, of the European Parliament and the Council, inserting an article 26b in Directive 2001/18/EC.[55] The General Affairs Council adopted on 23 July 2014 its first-reading position on the draft directive.[56] The adoption followed the political agreement reached in the Environment Council on 12 June 2014.

This so called a 'nationalisation' proposal has received a great variety of reactions, ranging from some Governments welcoming the proposal, to criticism that the proposal would go against the Internal Market and the WTO, and that it would affect the predictability of the system that various stakeholders (e.g. farmers and research organisations) need to make investments in this area.

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[54] COUNCIL OF THE EUROPEAN UNION, Interinstitutional File 2010/0208 (COD), 28 May 2014, 10271/14, p. 1–2.

[55] http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2010972%202014%20INIT

[56] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/144116.pdf. The Belgian and Luxembourg delegations abstained.

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Chapter 4
Genetic Technology and Food Safety: Country Report – Finland

Erkki J. Hollo

The article presents the basic principles and laws in relation to the legislation on food, especially genetically modified food (GMO) and foodstuff. The general Food Act has enacted provisions which apply also to GMO food. Some additional requirements are introduced in the Act on Gene Technology; this Act, however, does not contain any food-specific provisions others than labelling of products. International food obligations and the food legislation of the European Union is directly applicable and referred to in national law as binding legal sources. Finland has not created GMO free zones; on the other hand there are GMO cultivations on an experimental basis only.

General Information

Facts

The Finnish Ministry of Agriculture and Forestry, in charge of national food safety, states on its website: "Finland is internationally recognized as a country with high level of food safety. Food safety is ensured through coordinated actions all the way along the food supply chain. The basic responsibility for safety lies with businesses operating in the food chain. Official controls at municipal, provincial and national level together with controls on imported and exported foodstuffs ensure a high level of consumer protection. Reliable information plays a vital role, making it possible to trace products and giving consumers opportunities to make informed choices."[1]

[1] http://www.mmm.fi/en/index/frontpage/food_safety.html (February 15 2015).

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With this statement the Ministry indicates that Finland fully transposes and enforces its obligations under EU and international food law. As a consequence, the structure of national legislation on food safety is mostly the same as in EU law. Finland became member of the European Union in 1995.

Presently there is practically no GMO cultivation in Finland, partly due to climatic conditions. According to the Finnish Food Safety Authority (Evira) there are no GMO cultivated compounds on the market. In the fodder production the most commonly used GMO constituent is soya. Such products are labelled. Some seed grain is being tested for use. National GMO strategies focus mainly on scientific research in the field and on measures needed for adaptation to climate change. Presently there is no national or regional prohibition to cultivate or to use GMOs. The issue has entered the political floor, mainly on environmental grounds and in view of concern for the future of biological production. The agricultural sector seems to be in favour of GMO cultivation. Also scientific institutions have mostly adopted a supporting position; environmentalists refer to the proper interpretation of the precautionary principle as the main argument against use of genetically modified crop and food. There is certain scepticism against the free entrance of products approved in the EU but not so much for health concerns as for the mistrust for false labelling.

The Bill on GMO Production

In 2009, a Government bill for the production of GM crops (Bill No. 246/2009) was presented to the Parliament. The Bill does not set prohibitions or barriers to GM cultivation but there are specific requirements concerning location, pre-assessment, consents, permits and more. The proposal includes an option of voluntary agreement concerning the creation of GMO-free area. In 2011, an appeal was launched to the political parties of the Parliament, signed inter alia by a high number of academics, in order to favour equal coexistence of various production methods and against banning of GM technology in Finland.[2] According to the appeal, the "proposed government bill for the coexistence legislation puts cultivation of EU authorized GM varieties to a significantly poorer position compared to other cultivated crops. There is no scientific evidence for this discrimination of novel biological methods and it jeopardizes technological development, freedom of livelihood and the future of applied bioresearch in our country. – The bill does not take sufficient notice of the long-term work on the organization of coexistence in Finland carried out by the officially appointed group of Finnish scientific experts."

So far, the Bill has not been enacted by the Parliament, partly due to the reformed position of the European Union to genetic cultivation. On the other hand, the present

[2] News Report: http://www.hs.fi/english/article/High-level+delegation+asks+Parliament+to+ease+regulations+on+growing+genetically+modified+plants/1135263159290

government has not taken steps to make use of the EU possibility to prevent GMO cultivation. In Spring 2015, parliamentary elections will take place.

The Constitution

The Finnish Constitution (2000) declares certain basic rights: freedom of trade, right to property and environmental rights, i.e. the right to information, to participation and to access to justice in environmental matters (Sec. 15, 18 and 20). The guarantee of environmental rights is connected to environmental liability which is enacted in the Constitution as well (Sec. 20.1). This provision declares a responsibility of everybody for damage to environment, nature and biodiversity. In terms of food quality, the constitutional provision on environmental liability may serve as a basis for control and guidance. In fact, the Food Act comprises comparable provisions.

The environmental provision also, in line with the international Aarhus Convention on public environmental rights (UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters 1998), every citizen has the right to participate in environmental procedures and to obtain relevant environmental data. This right applies also to food production as far as environmentally induced impacts may be addressed (use of chemicals, pesticides etc.).

Those provisions may apply directly, but only exceptionally when there is a gap in material laws. Instead, the further enforcement of basic rights constitutes the need to adopt appropriate legislation. The freedoms and rights imply for instance that no permit is required for operations in agricultural activities. Conditions in relation to agriculture and cultivation may apply in funding and aid regimes but beyond those situations family farming is open to everyone and the mode of cultivation (normal biological, GMO) can be chosen without other limitations than those concerning marketing, labelling and public safety.

The Constitution does not provide for any specific human rights to food, obviously because there is no shortage in that respect. In cases of national emergency, exceptional flood or drought, and military conflicts, the national legislation on civil security provides for precautionary measures to be taken. That is a duty of the Government and does not invoke any actions from the side of citizens.

Definition and Legal Application of Food Safety

There is no explicit definition of food safety. The definition of food is defined by reference to Article 2 of the General Food Regulation (Food Act, 23/2006, Sec. 6). Food safety is, however, set as a all-over goal of the Food Act (Sec. 1): The objective of the Act is inter alia to “to ensure that food is safe and is handled safely, as

well as to ensure the health-related quality of food and that its quality in other respects accords with the food regulations". Since GMO food is not excluded from the scope of the Act the provisions also apply to those products. The criteria for GMO compounds follow the EU GMO Regulation and are administratively transposed in the Act on Gene Technology (377/1995).

Since GMO products and substances which passed the control procedure of GMO security (contained use) are by definition safe there is no additional specific assessment for GMO food foreseen. Additional obligations apply when placing GMO products on the market. There is an integrated safety regime connecting the provisions of the Food Act with those in the Gene Technology Act. As far as cultivated GMO products are concerned also the rules on appropriate management, precaution and coexistence apply. An additional feature in GMO food control is labelling.

Administration and Actors

Within the administration of the Ministry of Agriculture and Forestry, the Finnish Food Safety Authority (Evira) is responsible for enforcement and control of food safety. Finland has a centralized governmental system so there are no regions with legislative competence (with the exception of the autonomous Province of Åland but national food laws are in force there as well). Within the state administration, Regional State Administrative Agencies (AVI) are responsible for enforcement and control. Municipal food authorities are invested with direct power of control mainly under the guidance of Evira and its expert veterinarians.

Further organizations are the Agrifood Research Finland (MTT) and the Finnish Game and Fisheries Research Institute (RKTL), which were merged in January 2015 as the Natural Resources Institute Finland (Luke) and the Board for Gene Technology (GTLK) in the field of biotechnology within the administration of the Ministry of Social Affairs and Health. The Ministry of Employment and the Economy and the Ministry of the Environment play a role in matters falling in the field of their competence.

The Food Act enforces administratively the Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Further administrative national provisions are enacted by the Food Act as well. All enforced Regulations of the EU were listed in Sec. 3 of the Food Act.

According to the Gene Technology Act,[3] the Board for Gene Technology acts as the competent authority referred to in the Regulation (EC) No. 1946/2003 on transboundary movements of genetically modified organisms and in the Cartagena

[3] Finnish laws and related documents are available for free on www.finlex.fi. Most internationally relevant statutes are translated into English.

Protocol on Biosafety. Finland has ratified the Cartagena Biosafety Protocol in 2004. The provisions of the Protocol are applicable as national law.

The Gene Technology Act applies the publicity principle: all documents received or drawn up when attending to duties prescribed in this Act are subject to the provisions on publicity and confidentiality of documents laid down in the Act on the Openness of Government Activities (621/1999).

Outline of the Relevant Legislation

Transposition of Codex Alimentarius, Cartagena Protocol and Other International Agreements

Bill 53/2005 (Government's Proposal to the Food Act) states that the requirements of the Codex Alimentarius, including related instruments as the SPS regime of the WTO, are incorporated in the Food Act, as far as there is a need in view of the direct applicability of EU Food Regulations. For instance, the use of GMOs in fodder requires a risk assessment in accordance with Regulation (EC) 1829/2003. By means of legislative measures of the European Union Finland also follows the regulatory system of the WTO and the ECE. Finland has ratified the Cartagena Biosafety Protocol and it entered into force in 2004. The provisions of the Protocol are applicable as national law; therefore national decrees on e.g. fodder, animal food and more are in line with the Protocol without further mandate in law.

The Food Act enforces by its administrative provisions the Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Efficiency of enforcement will be supported by means of planning instruments, i.e. food safety strategies. Such plans shall be adopted yearly by the National Food Authority and followed up by regional supervising bodies. The EU Regulation (EC) No 1829/2003 on food safety foresees centralized union-wide risk assessment of GMO food products by the European Food Safety Authority (EFSA). This Regulation is administratively enforced by a ministerial Decree (910/2004) appointing the national contact point and the assessment of safety of food products.

According to the Gene Technology Act, the Board for Gene Technology acts as the competent authority referred to in the Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms and in the Cartagena Protocol on Biosafety.

Food Safety Guarantees

Since GMO food materials range under the regime of the Food Act the provisions referred to above also apply to genetically modified food and production. The control of genetic safety is administrated according to the Gene Technology Act as required by the corresponding EU Directives on contained use and placing on the market of GMOs (98/81/EC and 35/2004/EC).

Food safety control including GMO food stuff is submitted to legally manifested environmental principles in terms of production, marketing and rights of the public. The precautionary principle and ethical considerations are explicitly mentioned as objectives of the Gene technology Act. Its aim is

1. to promote the safe use and development of gene technology in accordance with the precautionary principle and in a way that is ethically acceptable; and
2. to protect human and animal health and the environment when carrying out the contained use or deliberate release into the environment of genetically modified organisms.

Additionally, all safety requirements set by the general food legislation apply to GMO food products as well. This is in line with the Cartagena Protocol, Codex Alimentarius and the WTO/FAO Agreements (TBT, SPS Agreement on Agriculture), including the Guidelines as well as the Hazard Analysis and Critical Control Point (HACCP).[4]

The Food Act regulates specifically the requirements concerning food, food producing animals, food premises and places of primary production (Chap. 2). Food must be fit for human consumption in terms of its chemical, physical, microbiological and health-related quality and composition and other properties, and must not present any hazard to human health or mislead the consumer. There are references also to the binding provisions on general requirements for food safety are also laid down in Article 14 of the General Food Regulation and in Article 4 of the General Food Hygiene Regulation. Provisions on requirements concerning the safety of food imported into and exported from the European Union are laid down in Articles 11 and 12 of the General Food Regulation. Provisions concerning foodstuffs from are equally enacted by reference to the requirements laid down in Article 3 of the Foodstuffs of Animal Origin Hygiene Regulation. Further provisions by Decree of the Ministry of Agriculture and Forestry are issued on:

1. food composition, the microbiological quality of food and contaminants contained in food,
2. external quality of vegetables;
3. food additives, flavourings, enzymes, nutrients and processing aids;
4. materials and articles intended to come into contact with food, as well as on their use and purity requirements.

[4] For the implementation of the principles see e.g. http://www.fao.org/DOCREP/005/Y1579E/Y1579E00.htm

At the grass roots the municipal sector has an important function of control (Food Act Sec. 32). For this purpose the organisation may be structured in various ways within a municipality or in groups of municipalities. A competent authority shall be appointed (municipal control authority). Its duty is to exercise food control in its area of operation.

In order to lighten the administrative burden, own-checks and the keeping of records concerning own-checks of primary production are used as modes of control (Food Act Sec. 19). Food business operators must possess sufficient and accurate information about the food they produce or process and distribute. Food business operators shall also be aware of the health hazards concerning food and the handling of food, and of the critical points in their operations in terms of food safety and other requirements under the Food Act.

Ethical Aspects

Ethical aspects are relevant in the environmental sector but even more in matters dealing with the modification of natural organisms. Therefore biotechnology is especially apt to ethical concern and criticism. Biotechnological applications often involve new inventions, research results and experiments the impacts of which require open and scientifically reliable analysis and discussion. In particular situations the public opinion may have political impacts on the development of GMO technologies or marketing of products.

In Finland, five expert bodies exercise ethical evaluation and studies of precautions from different aspects. the National Advisory Board for Biotechnology (BTNK) and the Board for Gene Technology (GLTK) which operate at a general level. Further there is the National Advisory Board on Health Care Ethics (ETENE), the National Advisory Board on Research Ethics (TENK). Ethical questions related to the release of information are dealt with by the Committee for Public Information (TJNK).

Guidelines

Three Ministries are invested with the competence to enact general guidelines for GMO control. Depending on the sector the Ministries are the Ministry of Social Affairs and Health (human health), the Ministry of the Environment (harm to the environment) and the Ministry of Agriculture and Forestry.

The Finnish Food Safety Authority (Evira) has published a Guideline on withdrawal of unauthorised genetically modified food and feed (10019/1, 1.12.2010). It is designed for use by food and feed sector operators and control authorities and it shows the different stages of administrative reaction. Evira has not been conferred legislative competence in this matter and cannot therefore issue binding regulations.

If food or feed placed on the market is found by authorities in a control inspection or by the food business operator himself to contain unauthorised GMO, or if information of this is received through the RASFF system (Rapid Alert System for Food and Feed), the operator must take immediate action. Depending on the situation, the operator must discontinue the sales of the product from stock and initiate procedures to withdraw the food or feed from the market. The operator shall also inform competent authorities about the matter. Evira informs the other member states of the EU about the matter through the RASFF system. The further processing of food and feed withdrawn from the market shall be agreed on with the control authority.

In actual cases authorities can apply the Guideline, lacking legal validity, on a risk-informed basis and according to the proportionality principle (Administrative Act, 434/2003, Sec. 6; in accordance with Control Regulation (EC) No 882/2004, Article 54). According to the proportionality principle, the regulatory action shall not exceed the level of necessity with respect to the severity of the violation and the possible risks caused by the product.

Novel Food

The concept of "novel food" comprises, in accordance with the EU Novel Food regulation 258/97/EC, food products that are prepared or complemented by genetically modified components. A national Decree (427/1997) prescribes the establishment of a novel food board to fulfil national obligations in accordance with the Regulation. The members of the board represent multi-scientific expertise especially in the fields of biology, medicine and biotechnology. The board examines applications aimed at the placing on the market of novel food products and prepares a preliminary assessment as prescribed by the EU Regulation. The final assessment is carried out by the EFSA, and the decision concerning the application is made at the European level. The board also gives its opinion about the applicability of the Novel Food Regulation. In addition a national authority is appointed by Decree for the reception of application.

The Gene Technology Strategy

A Working Group was appointed to prepare a strategy and Action Programme of the Ministry of Agriculture and Forestry for 2009–2013.[5] The Strategy and Action Programme presents the main principles, objectives and proposed measures for the

[5] Published as Memorandum 2009:6, Ministry of Agriculture and Forestry; http://www.mmm.fi/attachments/mmm/julkaisut/tyoryhmamuistiot/2009/5kMusGINE/gene_technology_strategy_2009-2013.pdf

use of gene technology in sectors governed by the Ministry; this includes the food sector. The working group states as follows:

> In the current, rapidly changing environment preserving the competitiveness of Finland's agricultural and food production is rooted in research and development based on new genetic know-how. Research in this field is rapidly advancing, and is a key focus area in most industrial countries. For Finland to remain at the forefront of development and to be able to meet the considerable challenges ahead will require adequate future investment in research based on new genetic know-how. This applies to agriculture as well. A significant future challenge from the viewpoint of agriculture and forestry, in particular, will be the adaptation to climate change.

The memorandum includes to improve the coordination of gene technology issues within the administrative sector of the Ministry of Agriculture and Forestry and cooperation with authorities outside the sector. It also specifies the main objectives and measures for plant and animal production, forestry, fishery, game husbandry, food production, consumer aspects and control of environmental impacts. Accordingly, the main objectives in terms of actions are adaptation to climate change, improved efficiency of bioenergy use, sustainable development and development of functional foods and foodstuffs. Within the listing of governing principles in the food sector it is stated that gene technology methods offer opportunities to promote and create new operating conditions for industries. "Applications must, however, be developed in such a way that the viability of different production sectors is ensured. Decision-making regarding approvals must, according to the memorandum be based on scientific risk assessment and precaution, including ethical aspects. The use of genetically modified products and the control of their marketing must be efficient, sufficient and equitable, and production chains must be transparent and traceable."

Decision-making on prior approval shall be based on high expertise, scientific risk assessment and precaution, including ethical aspects and the environmental impacts of genetically modified organisms shall be assessed. Control of the use of genetically modified organisms, the marketing of products containing these and the production chains is efficient, sufficient and equitable. Control systems and methods as well as distribution of labour and cooperation between the authorities are developed. In addition to precaution also prevention is whenever possible required.

However, while assessing risks in the context of food safety control unforeseen risks may and shall be taken into account with the consequences issued in the Food Act. As far as risk awareness is concerned, the type and extent of the activity practised by the food business operator as well as other factors with impacts on food safety and consumer protection associated with food must be taken into account when implementing obligations under food law and in controlling the compliance with them (Food Act Sec. 6 a). The Food Act also refers directly to the requirements on food safety as stipulated in EU provisions on general food safety requirements for in the General Food Regulation and the General Food Hygiene Regulation.

This implies a case-by-case assessment of the magnitude of risk of spread of GMOs or modified genes to the environment and of their introduction to cultivated or natural populations, as well as the resulting, possibly harmful impacts which

research indicate as risk factors. In Finland, particular regard has been given to the special properties and ecological impacts of different groups of organisms (micro-organisms, plant and animal groups) which affect the possibilities for GMO use in reducing the negative environmental impacts of agriculture, such as fertiliser emissions and erosion, and induce environmental impacts of the cultivation recommendations of herbicide or pesticide resistant genetically modified crops.

Admission of GMO in Food Production

The Food Act includes no specific provisions on GMO substances in food; instead, the Act refers in full to EU Regulations. In addition, there are a number of health and other requirements concerning food premises, storage, transportation and more (Food Act Sec. 10–11). Before a genetically modified organism or a combination of such organisms as a product or contained in products is placed on the market in Finland the operator shall submit to the Board for Gene Technology an application for consent for it. Risk assessment is mandatory, and covers substances apt to be used in food and fodder materials. The operator shall, when carrying out the contained use of genetically modified organisms and the deliberate release into the environment of genetically modified organisms, make a risk assessment with a view to preventing any adverse effects on health and the environment.

When there is a need to apply for a food permit or to notify a product the Gene Technology Act requires a valid labelling. There shall be at all stages of the placing on the market of genetically modified organisms a mention on the labelling of the product or in the accompanying document that "This product contains genetically modified organisms", unless otherwise provided elsewhere (Sec. 21 c). It has to be ensured, in addition, that the labelling and packaging of the genetically modified organisms as products or in products placed on the market comply at all stages of the placing on the market with the requirements specified in the written consent. Changes in the composition or use of the product must be notified and approved by the competent authority.

There are no additional national thresholds for GMO food products, as there is no production for the market. Threshold values may, however, be adopted as guidelines on the ground what is technically feasible. In regard to the products that contain minor amounts of authorized genetically modified organisms that are adventitious or technically unavoidable, a minimum threshold may be established by decree of the Ministry of Social Affairs and Health.

Implementation and Enforcement, Controlling Regime

General Aspects of Food Control

As stated above, all elements of EU legislation on food products and the use of genetically modified products has been accurately transposed by national laws and by references to EU Regulations as these are directly applicable without national transposition. The modes enforcement are integrated in the general control mechanisms and administrated by specified competent supervising bodies.

Pursuant to Article 4 of Regulation (EC) No 1829/2003 on genetically modified food and feed, the safety of foods and feeds containing, consisting of or produced from genetically modified organisms (GMO) must be assessed before they are placed on the market within the Community.

According to the Food Act (Sec. 47) the Finnish Food Safety Authority (Evira) shall draw up a national food control programme to steer and coordinate the control performed under this Act.

The control programme shall contain at least the following information:

1. specification of the content of inspections;
2. the criteria for assessing the risks at different types of control sites and for determining the frequency of inspections;
3. assessment of the need for sampling;
4. methods for assessing the implementation of control plans; and
5. methods used in assessing the implementation of the control programme.

Administrative Control of GMO Products

In 2013, the National Agency has conducted a test in order to determine the load of GMOs in food products. The sample was focused on food products containing soya, rice and corn. Using the limit value of 0,9 % as a guideline, no excess was found in the samples (10 by number). However, in 30 % of the products there was a positive load of GMO.[6] Also, in three cases the package labels were not marked properly in Finnish and Swedish.

The supervisory authorities referred to in the Gene Technology Act this Act are the National Supervisory Authority for Welfare and Health, the Finnish Environment Institute and the Finnish Food Safety Authority (Sec. 5 g).

> The inspectors of the supervisory authorities are in charge of the supervision of compliance with the Act and the provisions and decisions issued in virtue of it. An inspector appointed by the supervisory authority shall have good knowledge of gene technology and the abilities and skills required to carry out the duties. The actions of the inspectors are subject to

[6] Source: http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/tuotantotapoja/muuntogeeniset+elintarvikkeet/valvontatulokset+vuonna+2013/

> what is provided by applicable statutes regarding the disqualification of authorities and arranging the interpretation and translation that is the responsibility of authorities in administrative matters…

There are three stages of illegality which administrative sanctions depending on the severity of the violation. First, the basic rule for the control of genetically modified products is found in Section 22 of the Gene Technology Act (Actions contrary to the provisions and restriction and prohibition of use):

> If the operator violates this Act or provisions issued in virtue of it, the Board for Gene Technology[7] or the supervisory authority may order the operator to fulfil the obligations laid down in the Act or in provisions issued in virtue of it. If it is found after the submitting of a notification or an application in accordance with this Act that a genetically modified organism can cause considerable harm to human or animal health or to the environment, the Board for Gene Technology may on its own initiative or on the initiative of the supervisory authority:
>
> 1) restrict the taking into use of the installation or its part or the contained use of genetically modified organisms;
> 2) restrict the deliberate release for any other purpose than for placing on the market; or
> 3) prohibit the operator to continue a procedure violating the provisions, if the measures referred to in subparagraphs 1 and 2 do not result in a sufficiently high level of protection.

Secondly, if the supervisory authority or the Board for Gene Technology (licencing authority) finds out that a product may constitute a serious hazard to human or animal health or to the environment, it shall suspend the placing on the market of the product and inform the public thereof. The supervisory authority shall inform the Board for Gene Technology thereof. The Board shall inform the Ministry of Social Affairs and Health, which shall bring the matter to the plenary session of the Government for consideration.

Third, The Government may provisionally restrict the use or sale of a genetically modified product, or prohibit its use or sale within the territory of Finland, if the supervisory authority or the Board for Gene Technology has after the granting of the consent obtained information that has significant consequences with regard to the risk assessment, or on the basis of which the Board for Gene Technology or the supervisory authority finds out that the product or a genetically modified organism in the product may constitute a serious hazard to human or animal health or to the environment. (Sec. 24)

Publicity of Information and Labelling

The Gene Technology Act applies the publicity principle: Any documents received or drawn up when attending to duties prescribed in this Act are subject to the provisions on publicity and confidentiality of documents laid down in the Act on the

[7] Licensing authority.

Openness of Government Activities (621/1999). Some information is not considered confidential if that would jeopardize efficient control.

Finland applies Directive 2000/13/EC on Food Labelling. According to national law (Food Act Sec. 9) requirements are enacted to insure open and truthful information of food products to consumers. In food packaging, presentation and advertising, or in some other way in connection with marketing:

1) information given about food must be truthful and it must be sufficient in view of the requirements of the Food Act;
2) information given about food must not be misleading;
3) food must not be presented as having properties related to prevention, treatment or curing of human diseases or refer to such information, unless otherwise provided elsewhere in the law. Provisions on prohibiting the issue of misleading information are also laid down in Article 16 of the EU General Food Regulation.

As far as labelling is concerned, the Gene Technology Act stipulates that there shall be at all stages of the placing on the market of genetically modified organisms a mention on the labelling of the product or in the accompanying document that "This product contains genetically modified organisms", unless otherwise provided elsewhere (Sec, 21 c). It has to be ensured, in addition, that the labelling and packaging of the genetically modified organisms as products or in products placed on the market comply at all stages of the placing on the market with the requirements specified in the written consent. In regard to the products which contain minor amounts of authorized genetically modified organisms that are adventitious or technically unavoidable, a minimum threshold may be established by decree of the Ministry of Social Affairs and Health below which these products need not be labelled according to the referred provision.

If the constituent is described as a group, for instance "spice mix", the list shall contain the mark "contains GMO" or "contains substance X produced of GMO". If there is no constituent list, label shall clearly indicate genetically modified compounds. Labels shall always indicate a GMO concentration exceeding 0,9 %. If food or fodder is composed of more than one constituent, the list of constituents shall immediately after the main constituent indicates the mark "genetically modified". In addition, the labelling and packaging of the genetically modified organisms as products or in products placed on the market shall comply at all stages of the placing on the market with the requirements specified in the written consent.

Consumer protection is the basis for the rulings of the Food Act. Competition law does not foresee specific provisions in this respect. The Competition Act (948/2011) sets restraints to prohibited competition (Sec. 5). All agreements between undertakings, decisions by associations of undertakings, and concerted practices by undertakings which have as their object the significant prevention, restriction or distortion of competition or which result in a significant prevention, restriction or distortion of competition shall be prohibited (Sec. 5). However, these prohibitions do not apply to arrangements by agricultural producers, associations of agricultural producers, sector-specific associations and any associations formed by these sector if the arrangement fulfils the substantive requirements established in accordance with Section 42 of the Treaty on the Functioning of the European Union,

under which the rules on competition of Articles 101 and 102 of the said Treaty shall not apply. In view of labelling, false information could constitute an element in the determination if an undertaker holds a dominant position or not (Sec. 4).

Sanctions

Food Law has no specific sanctions for different types of infringements against food legislation. The regulatory system is instead comprehensive for the entire sector, including GMO foodstuff. Mostly the coercive administrative sanctions follow the generally applicable structure with threats, fines, penalty payments and prohibitions (Food Act Sections 63–66). In addition there are directly applicable measures, as for instance withdrawal of a product from the market. This is the case especially when the product is found to contain unauthorised GMO for which an authorisation application has not been submitted. Equally, products already supplied to buyers must be recalled, because the safety of the GMO has not been assessed (General Food Law Regulation (EC) No 178/2002, Articles 7 and 19). If food or feed placed on the market is found by authorities in a control inspection or by the food business operator himself to contain unauthorised GMO, or if information of this is received through the RASFF system (Rapid Alert System for Food and Feed), the operator must take immediate action. Depending on the situation, the operator must discontinue the sales of the product from stock and initiate procedures to withdraw the food or feed from the market.

Infringements against Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms is sanctioned by the general provisions of Food Act; these include, in addition to prohibitions and threat of fine, e.g. following (Sec. 55):

> If food or information given about it, the food production, processing or distribution stage, food premises, a place of primary production, or the operations practised in them may cause a health hazard, endanger the accuracy or sufficiency of the information given on the food, mislead the consumer, or otherwise violate the food regulations, the control authority may order the deficiency to be removed. A violation of the regulations shall be ordered to be removed immediately or within a fixed period specified by the control authority.

The Finnish Food Safety Authority may prohibit a food business operator from continuing to conduct marketing that violates the food regulations or from resuming such or similar marketing. The prohibition may also be given as temporary, in which case it remains in force until the Finnish Food Safety Authority has issued its final decision on the matter. If in the marketing of food information is given that may cause a serious health hazard or if the marketing of food is essentially incorrect or misleading, the Finnish Food Safety Authority may take special measures.

Liability for Genetically Modified Products

Food-Specific Liability

The Governmental Bill for an Act on genetically modified plant production (246/2009), which was referred to above, but which did not reach the stage of legislation, introduces rules on liability for damages. Without such a legislation producer's (farmer's) liability could occur on a basis of illegal action or negligence only. Generally, the Finnish system is partly based on tort law (Tort Liability Act 412/1974) and special statutes on strict liability. The Damages Act applies whenever an action or omission was deliberate or negligent. This Act has a broad applicability in civil, public and criminal law. Tort law follows here Nordic and Continental principles on causality and fault.

This prerequisite would normally not occur in cases of GMO farming because there is no prohibition of GMO farming or, on the other hand, a prescription to use a certain mode of farming. From the point of civil or public legality, different types of farming stand at an equal level. In case of environmental pollution strict liability is enacted for any kind of farming (Act on Compensation for Environmental Damage 737/1994).

According to the Gene Technology Act there are three different bases for civil liability, two of them (environmental and producer liability) apply strict liability. Compensation for damage to the environment arising as a consequence of activities referred to in the Act is subject to the provisions concerning strict liability for environmental damage (Act 737/1994). Compensation for loss caused by a product containing genetically modified organisms to a person or to property intended for private use or consumption and used by the injured party mainly for such purpose is subject to the provisions of the Product Liability Act (694/1990). Compensation for other loss caused by activities is subject to the provisions of the Tort Liability Act (412/1974). The operator is liable to compensate for such loss, even if it was not caused wilfully or through carelessness.

Criminal liability for each category of activity under the Gene Technology Act is sanctioned in the Penal Code. Administrative coercive measures apply as generally in administrative law.

Liability for damages caused by genetic farming to biological or normal farming is therefore exceptional and related to economic market losses. In that sense the issue is about market compensation in a competitive context. Since weather conditions may influence the extent of GMO impacts on other cultivations and legal liability would normally not apply in such situations, the problem is how to determine the criteria for this exceptional category of liability.

The discussion in different countries elucidates various possibilities to compensate the loss to farmers; insurance, GMO cultivation fees, State aid have been mentioned as models. The Bill is based on the civil liability rule: the GMO farmer causing damage to other farming is liable for the damage. Liability would presuppose a certain degree of negligence in relation to the observation of enacted rules on

GMO farming, i.e. distance and zone restrictions. Additionally the loss is compensable only if there is a market loss; such a loss may consist of an increase in the "purity level" of biological products (0,9 %). If the economic loss is due to measures taken by administrative regulations and orders, the State would be liable on a discretionary basis.

Product Liability

A main principle in consumer law is the prohibition to provide false information and the requirement of truthful information. The basis for liability may occur as follows.

The Consumer Protection Act (38/1978) establishes liability for compensation for losses due to a defect in the goods. Also indirect losses shall be compensated but only if the defect or loss is due to negligence attributable to it or if, at the conclusion of the contract, the goods differed from an express representation of the seller (Sec. 20). Additionally, property losses may be compensated: If a defect of the goods causes damage to property other than the goods that were sold, the liability of the seller covers only if the damage is caused to property with a direct connection of use to the goods sold (Sec. 21).

The Unfair Business Practices Act (1061/1978) provides for public control (prohibitions, orders) and criminal sanctions. Civil liability is based on the general Tort Liability Act (412/1974); precondition for liability is the provider's intention or negligence to gain profit at someone else's cost.

The Product Liability Act does not include any specific provisions on food products or GMO materials. Therefore the general provisions apply analogically to the food sector as well. Liable parties include:

(1) the party which has manufactured or produced the product which has caused the injury or damage;
(2) the party which has imported the product into the European Economic Area with the intention of putting it into circulation there; as well as
(3) certain other situations of import based on international legislative commitments of Finland. The damages under this Act shall be determined, where appropriate, in accordance with the Tort Liability Act 412/1974.

Some Summarizing Aspects

In Finland, the genetically modified food production has not entered the market to the extent that problems or severe concerns would have arisen. The use of gene technology in agriculture, forestry, fishery and food production is developed in a customer- and environmentally-oriented way, and aimed at higher quality and more diversified products.

Use and marketing of genetically modified products is based on the prior approval procedure, whereby permission is granted only after these products have been proven to be safe to humans, animals and the environment.

Decision-making on prior approval is based on high expertise, scientific risk assessment and precaution, including ethical aspects. The environmental impacts of genetically modified organisms are assessed. Uncontrolled release of genetically modified organisms to the environment and the possible ecological damages caused by this are prevented.

Control of the use of genetically modified organisms, the marketing of products containing these and the production chains is efficient, sufficient and equitable. Control systems and methods as well as distribution of labour and cooperation between the authorities have been developed.

The maintenance and development of multidisciplinary scientific expertise required for the application of gene technology in the agriculture and food, forestry and fishery sectors is supported by research. Research and development work, as carried out in specialized bodies, emphasises the importance of international cooperation and innovative know-how.

To ensure sufficient customer information and choice, genetically modified food products are appropriately labelled. Production chains must be transparent and traceable with respect to the origin, production method, composition and quality of products. As a whole, preparatory development and decision-making relating to gene technology in the food sector is open and transparent, and the communication system works properly.

Essential National Legislation

Administrative Act (434/2003)
Act on Compensation for Environmental Damage (737/1994)
Competition Act (948/2011)
Constitution (731/1999)
Consumer Protection Act (38/1978)
Food Act (23/2006)
Gene Technology Act (377/1995)
Act on the Openness of Government Activities (621/1999)
Product Liability Act (694/1990)
Tort Liability Act 412/1974
Unfair Business Practices Act (1061/1978)
Governmental Bill No. 246/2009

Chapter 5
Regulating Genetically Modified Organisms in Ireland: A Laissez Faire Approach? – Country Report: Ireland

Mary Dobbs

This chapter examines the legal framework applicable to genetically modified organisms (GMOs) in Ireland, bearing in mind the limited presence of GMOs. As a member of the European Union (EU), a specific, process-based regime applies regarding the authorisation and regulation of GMOs. This is intended to ensure a high level of environmental and human health protection and also enable producer and consumer choice. This regime is highly harmonized, but allows some flexibility regarding its implementation and, soon, the potential to opt-out from cultivation in part or entirely. Although, Ireland has only legislated on the area to the extent and in the manner required by the EU, it may avail of the opt-out in future – understandable in light of the lack of any cultivation currently and the green image of Ireland.

Complementary horizontal legislation and common law principles, relevant to labelling and varying forms of liability, deal with most issues that might arise quite comprehensively. However, they are quite complicated, overlapping and untailored and it is worth considering whether specific legislation should be developed to deal with liability related to GMOs.

Overall, Ireland holds varying stances to different forms of GMOs, with the greatest **acceptance** and use of GM-feed for pragmatic reasons. It has not developed a specific Irish approach, copy-pasting EU legislation and relying upon existing law to deal with any issues. This is understandable in light of the high level of harmonization and limited presence of GMOs in Ireland, but nonetheless will need to be developed as the availability of GMOs increases.

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Introduction

> Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life (Wold Food Summit 1996).

As genetically modified organisms (GMOs) are utilised in food production, their presence and role is clearly of significance to the fundamental issue of food security.[1] They may increase the quantity, quality or indeed variety of food available or make it more accessible (physically or economically, in the short and long term). This for instance can be through adapting the crops to grow in challenging conditions, increasing the nutritional value or just increasing competitiveness amongst producers. However, GMOs also bring potential threats, in the eventual products as with other novel foods and also in their impact on the environment and other agricultural produce as with other agri-types. These threats are increased by the scientific uncertainty that surrounds GMOs, the difficulties in calculating the rate of out-crossing and the impact upon non-target organisms. Furthermore, the nature of the environment and agricultural production make it very difficult to undo any previous admixture. Hence, one sees countries such as Australia being extremely restrictive in their controls on the importation of any living organisms, whether GM or non-GM. Consequently, it is essential to consider carefully the regulation of GM food, feed and cultivation and be proactive in developing approaches locally, nationally and internationally.

In light of Ireland's image as the Emerald Isle and the traditional significance of agriculture economically and culturally, as well as the famine or 'Great Hunger' in the nineteenth century, one might expect that food security would be evident across policies and legislation of all levels. Further, it might be expected that Ireland would be proactive in developing policies surrounding new forms of agricultural production, including GM crops. However, food security is not expressly found within domestic policies or legislation and the Irish legislation specifically addressing GMOs is primarily implementing and therefore somewhat replicating the relevant sectoral legislation at the EU level. The lack of specific Irish law and policy dealing with GMOs can be understood in light of the minimalistic presence of GM crops in Ireland and also the high level of harmonisation by EU legislation.

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[1] E.g. J Tait and G Barker, 'Global food security and the governance of modern technologies' (2011) 12:8 EMBO Reports, 763; M McGloughlin, Ten reasons why biotechnology will be important in the developing world' in R Sherlock and JD Morrey (eds), *Ethics in Biotechnology* (Rowman and Littlefield Publishers, 2002); MA Altieri and P Rosset, 'Ten reasons why biotechnology will not ensure food security, protect the environment, or reduce poverty in the developing world' in Sherlock and Morrey; M Qaim, 'Benefits of genetically modified crops for the poor: household income, nutrition and health' (2010) 27:5 New Biotechnology, 552; and H Azadi and P Ho, 'Genetically modified and organic crops in developing countries: A review of options for food security' (2010) 28:1 Biotechnology Advances 160.

This report considers briefly the overall Irish approach in policy and law regarding "Food security" and the presence of "GMOs in Ireland", before looking in some more depth at the Irish legal framework for GMOs. The general framework will be outlined (section "GMO legislative regime in Ireland"), before considering specific components regarding "Authorisations and restrictions of GMOs in Ireland", the general "Regulation of the regime", "Labelling" and "Liability".

Food Security

As noted, there is no Irish legislation addressing food security directly. The concept however is present within a number of official documents, specifically regarding international food security, and is reflected in Ireland's participation in international organisations and signing a range of significant documents. For instance, Ireland is a member of the UN Food and Agricultural Organisation (FAO) and the UN World Food Programme and ratified the International Covenant on Economic, Social and Cultural Rights (ICESCR).[2] The UN's first Millennium Goal is to eradicate extreme poverty and hunger[3] and, in this regard, Ireland provides cash contributions to the WFP to facilitate food aid.[4]

The UN Economic and Social Council formulated General Comment 12 on the Right to Adequate Food in 1999, which imposes obligations upon states that are reflected in the FAO Voluntary Guidelines on the Right to Food, November 2004. Obligations include negative ones (not to arbitrarily deprive people of their right to food) and positive ones (to facilitate and promote access and utilisation), which together will promote food security nationally and internationally. Ireland is also a signatory of these Guidelines.

Continued Irish support for global food security is visible in its White Paper on Irish Aid in 2006, which dealt with global hunger and poverty[5] and is currently undergoing a review.[6] Furthermore, President Higgins in January 2013 re-emphasized the importance of global food security at a conference on 'Feeding the

[2] The ICESCR contains numerous rights, including ones related to an adequate standard of living (Article 11) and therefore 'adequate food' (Article 11, para 1) and 'freedom from hunger' (Article 11, para 2). The right to adequate food is considered by the Committee to be fulfilled 'when every man, woman and child, alone or in community with others, have physical and economic access at all times to adequate food or means for its procurement'. Committee on Economic, Social and Cultural Rights, 1999, General Comment 12: The Right to Adequate Food, UN Doc. E/C/12/1999/5, available at: http://www.unhchr.ch/tbs/doc.nsf/0/3d02758c707031d58025677f003b73b9

[3] http://www.un.org/millenniumgoals/poverty.shtml

[4] E.g. http://www.agriculture.gov.ie/agri-foodindustry/euinternationalpolicy/internationalfoodsecurity/

[5] http://www.irishaid.gov.ie/media/irishaid/allwebsitemedia/20newsandpublications/publicationpdfsenglish/white-paper-english-2006.pdf, in particular at 51–2.

[6] http://www.irishaid.gov.ie/about-us/our-policies/white-paper-on-irish-aid/

world in 2050'.[7] He noted Ireland's commitment to the Right to Food and also the importance to bear in mind the special nutritional needs of vulnerable groups, requiring strong communication and linkages between the agriculture and health sectors in order to ensure the three pillars of food security-availability, access and utilisation.

Although there is no national definition of food security, as a member of the FAO, the understanding of food security[8] within the organisation is of importance for Ireland. This focuses upon the simultaneous requirements of: 'physical availability of food'; economic and physical access to food'; 'food utilization'; and the stability of these three aspects over time.

Using these as a starting point and looking inwards, it is possible to see these elements reflected generally to varying degrees in Ireland's welfare policies, but also in its Constitution (Bunreacht na hÉireann). Ireland's Constitution focuses on primary rather than secondary or tertiary rights, which therefore makes it challenging to identify relevant constitutional rights. Nonetheless, although the Irish constitution contains no express right to food, Article 45.2.i[9] states that the *'State shall, in particular, direct its policy towards securing:- i That the citizens (all of whom, men and women equally, have the right to an adequate means of livelihood) may through their occupations find the means of making reasonable provision for their domestic needs.'* The main difficulty with this provision is that it is part of the 'Directive Principles of Social Policy' and is unenforceable before the Courts-it is of guidance to the national parliament only.[10] Overall, although Ireland is a welfare state and has long-standing policies attempting to address food poverty nationally[11] and assist in food security internationally, there is little to be found in the legislation or Constitution imposing relevant general obligations or providing enforceable rights.[12]

In light of this, it is perhaps unsurprising that there is nothing in the legislation dealing directly with the relationship between genetic technology and food security. Furthermore, documents such as the White Paper on Irish Aid do not deal with

[7] http://www.president.ie/speeches/facing-the-challenge-of-feeding-the-hungry-of-the-world/. It should be noted that, whilst an important political statement, the President does not have powers regarding the creation or implementation of law and nor do his views bind the legislative or executive.

[8] FAO, An Introduction to the Basic Concepts of Food Security, 2008: http://www.fao.org/docrep/013/al936e/al936e00.pdf

[9] Other relevant provisions include Articles 40 and 43 regarding property rights.

[10] E.g. *T.D. v Minister for Education* [2001] 4 IR 259.

[11] Although strong criticism exists in relation to its efforts in Ireland in practice, e.g. EA Dowler and D O'Connor, 'Rights-based approaches to addressing food poverty and food insecurity in Ireland and UK' (2012) 74:1 Social Science and Medicine 44.

[12] For further discussion of the issues of food poverty and food (in)security in Ireland, see for example: S Friel and C Conlon, *Food Poverty and Policy*, (2004) Combat Poverty Agency, available at: http://www.cpa.ie/publications/FoodPovertyAndPolicy_2004.pdf; and D O'Connor, S Cantillon and J Walsh, *Rights-Based Approaches to Food Poverty in Ireland*, (2011) Combat Poverty Agency, available at: http://www.cpa.ie/publications/workingpapers/2011-01_WP_RightsBasedApproachesToFoodPoverty.pdf

genetic technology. Nonetheless, there is clearly a link in practice between the two issues and hence it is crucial to understand the legal regime for GMOs in Ireland.

GMOs in Ireland

Before considering briefly the relevant law applicable to GMOs in Ireland, it is worth noting the current attitude towards and use of GMOs in Ireland. Generally the Irish governments have taken a 'positive but precautionary approach' to the use of GMOs.[13] In 2009, a coalition government that included the Green Party stated that it would aim for a GM-free Ireland. Following the departure of the Green Party from the coalition, the government relaxed its position in relation to GMOs.[14] The current position is more positive and essentially supports the position at the EU level, facilitating authorisations of GM food, feed and crops following risk assessments in accordance with the precautionary principle, where previously Ireland would have abstained.[15] Nonetheless, the general stance remains one that favours GM-free cultivation within Ireland.[16]

As it stands, there is no GM cultivation within Ireland and only one crop is currently authorised within the EU for cultivation. One field trial of sugar beet by Monsanto was authorised in Ireland and the authorisation was upheld by the High Court in 1999.[17] A further trial was authorised for BASF in relation to potatoes with a gene inserted to provide protection from blight.[18] However this was not carried out and BASF carried out the trials in other Member States instead. In July 2012, the Environmental Protection Agency (EPA) authorised Teagasc to carry out field trials on GM blight resistant potatoes.[19] Some areas of Ireland have declared themselves as GM-free,[20] although it should be noted that such declarations are not enforceable currently under EU law as a matter of course. However, Directive 2015/412 came into force in spring 2015 and allows for Member States to opt-out from cultivation

[13] E.g. 'An Action Programme for the Millennium', (2000) Department of the Taoiseach, available at: http://www.taoiseach.gov.ie/eng/Publications/Publications_Archive/Publications_for_2000/actionprogprogressyear3jul2000.pdf at 33.

[14] http://www.rte.ie/news/2011/0411/299748-food/

[15] E.g. Department of Agriculture, Fisheries and Food, 'Brief for Minister for Agriculture, Fisheries and Food', March 2011, available at http://www.agriculture.gov.ie/media/migration/publications/2011/briefforministermarch2011/Chapter%204%20Main%20Brief%20Part%201.pdf at 54–6.

[16] E.g. 'Brief for Minister for Agriculture, Fisheries and Food', *ibid* at 62.

[17] *Watson v EPA and Monsanto*, judgment of O'Sullivan J, 6 October 1998.

[18] EPA website: http://www.epa.ie/pubs/reports/other/gmo/field/EPA_gm_potato_field_trial.pdf. Consent for notification no. B/IE/06/01, GMO Register Number 208, dated 4th May 2006.

[19] EPA website: http://www.epa.ie/licensing/gmo/fieldtrial/. Consent for notification no. B/IE/12/01, GMO Register No. G0469-01, dated 25th July 2006.

[20] Map and details of self-declared GM-free areas in Ireland in 2010: http://www.gmfreeireland.org/map/index.php

where the relevant criteria are met (see below).[21] Although Ireland did raise concerns, these related to technical aspects and not the overall aim of the proposal.[22] Indeed Ireland was part of the group of Member States who requested that such an approach be considered[23] and it seems likely that Ireland will avail of it if possible.

The lack of GM cultivation has an impact upon the presence of GMOs in food and feed within Ireland, but does not lead to its absence.[24] There is the potential for GM feed to be given to animals in Ireland, which eventually results in some form of food being consumed in Ireland or exported, e.g. meat, eggs, and milk. Legally, generally only GM feed authorised in the EU can be used in Ireland. According to official figures in 2010, approximately 2.3 tonnes of the raw materials used in compound feed in Ireland were from GM crops authorised in the EU and more than 90 % of protein feed for livestock contained EU authorised GM varieties.[25] There is concern that the difficulties in avoiding admixture with GMOs authorised in source countries for feed, but not in the EU, increase financial and competitive challenges for Irish producers.[26] Ireland indicated support for the EU proposal to tolerate low levels in feed imports of GMOs as yet unauthorised in the EU, in specific circumstances.[27] Since then, Article 2 of Regulation 619/2011/EC[28] provided for a temporary tolerance of unauthorised GM feed to be 0.1 %, rather than an absolute zero, in limited circumstances. It should be noted that produce from animals fed with GM feed does not count as GM and does not have to be labelled as such, although it will impact upon other labelling, e.g. organic produce.[29]

Data gathered in EU surveys in 2010 provides an insight into general public opinion in the EU and in specific Member States.[30] Although opinion in Ireland in relation to GM food was more favourable than in many other Member States, it was

[21] Directive 2015/412/EU of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, [2015] OJ L68/1.

[22] Council of the EU, Progress Report on a Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, 2010/0208 (COD), Brussels, 3 June 2012, available at: http://register.consilium.europa.eu/pdf/en/12/st10/st10883-re01.en12.pdf at 5.

[23] Council of the EU, 'Genetically Modified Organisms-A Way Forward-Information from the Austrian delegation', Brussels, 24 June 2009, 11226/2/209 REV 2, http://register.consilium.europa.eu/pdf/en/09/st11/st11226-re02.en09.pdf

[24] List of GMOs authorised for GM food and feed products in EU and therefore in Ireland, available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

[25] 'Brief for Minister for Agriculture, Fisheries and Food' (n15), at 110.

[26] 'Brief for Minister for Agriculture, Fisheries and Food', (n15), at 110.

[27] 'Brief for Minister for Agriculture, Fisheries and Food', (n15), at 56.

[28] Regulation 619/2011/EC of 24 June 2011 laying down the methods of sampling analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired, [2011] OJ L166/9.

[29] For discussion on labeling, see section "Labelling" below.

[30] http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_winds_en.pdf

still not positive. Nonetheless, although GM food is not readily apparent in large quantities in stores, a range of GM foods are authorised at the EU level and therefore in Ireland. Some GM food is present in the country, as clearly indicated by monitoring demonstrating that products in stores were mislabelled and should have had GM labels on them.[31]

Consequently, the Irish approach to GMOs is quite mixed and somewhat contradictory. It is ambivalent towards GM cultivation, seemingly in favour of GM feed and on balance against GM food. Considering the lack of GM cultivation currently and the limited scope for national action in the area, it is hardly surprising that there is limited Irish law dealing with the area as we shall now see.

GMO Legislative Regime in Ireland

Considering first relevant international law, Ireland is a member of the Codex Alimentarius (voluntary standards) and of the WTO, as is the EU. As a result of its membership of the WTO, the General Agreement on Tariffs and Trade (GATT), the Sanitary and Phytosanitary (SPS) Agreement, and the Technical Barriers to Trade (TBT) Agreement all apply to Ireland and the EU. Their relevance to GMOs and the issue of food security was amply demonstrated by the Biotech Dispute.[32] Similarly Ireland has ratified the Cartagena Protocol on Biosafety to the UN Convention on Biological Diversity and also the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.[33] The latter Protocol is not in effect yet, as an insufficient number of States have ratified it. However, although of influence, raising the possibility of international liability and having knock-on effects (e.g. through impacting upon EU law), due to Ireland's dualist nature, the Agreements and Protocols are not actually part of Irish law unless incorporated directly.

The main supranational law of direct relevance is the EU legislation on GMOs and in particular Directive 2001/18 on Deliberate Release,[34] Regulation 1829/2003 on GM food and feed[35] and Regulation 1830/2003 on labelling and traceability of GMOs.[36] These are implemented in Ireland by: the 2003 Deliberate Release

[31] http://www.fsai.ie/enforcement_audit/monitoring/surveillance/genetically_modified_food_surveillance.html

[32] 'European Communities—Measures Affecting the Approval and Marketing of Biotech Products', WT/DS291/R, WT/DS292/R and WT/DS293/R, DSR 2006:III, 847.

[33] It should be noted that these focus on the release of GMOs in to the environment, rather than specifically upon GM food or feed.

[34] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, [2001] OJ L106/1.

[35] Regulation 1829/2003/EC of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, [2003] OJ L268/1.

[36] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the trace-

Regulations,[37] the 2004 GM Feed Regulations[38] and the 2013 GM Food Regulations.[39] The EU laws provide for the prior authorisation, monitoring, tracing, labelling, safeguard procedures and general management of GMOs for cultivation and use for food and feed. They work in conjunction with other provisions of a horizontal nature that deal with aspects such as labelling, risk assessments, comitology procedures and principles. The national legislation provides for the implementation and enforcement of the provisions in the EU laws.

Relating to food law more generally, Ireland has a range of relevant legislation including regarding testing, criteria for specific types of food, additives and contaminants, e.g. the Food Safety Authority of Ireland Act, 1998 and Part V of the Health Act, 1947.[40] However, the key piece of EU law is Regulation 178/2002 (the General Food Law),[41] which is of horizontal application and generally requires that all food and feed be safe for humans and animals (Articles 14 and 15). It also established the European Food Safety Authority (EFSA). It is of relevance to labelling law also. This is implemented in Ireland by the 2007 General Food Law Regulations.[42]

Also relevant are the labelling rules of EU and Irish and origin outlined in section "Labelling" below, which are primarily based on the Consumer Protection Act 2007, the EU and Irish GMO laws, the 2002 Labelling Regulations,[43] the 2009 Food and Feed Hygiene Regulations,[44] the EU's Regulation 834/2007/EC on organic production and labelling of organic products[45] and Ireland's corresponding 2004 Organic Farming Regulations (as amended).[46]

The legislation is further complemented by a number of relevant legal principles within the case-law and secondary legislation, e.g. proportionality, prevention and precaution. In Irish law, proportionality is a fundamental principle. However, it is questionable whether there is a general obligation (under Irish law) to apply prevention and precaution across all regimes where relevant unless precedent or specific

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ability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, [2003] OJ L268/24.

[37] Genetically Modified Organisms (Deliberate Release) Regulations 2003, S.I. No 500/2003.

[38] European Communities (Feeding stuffs) (Genetically Modified Feed) Regulations 2004, S.I. No 424/2004.

[39] European Union (Genetically Modified Foodstuffs) Regulations 2013, S.I. No 268/2013.

[40] More generally see: http://www.fsai.ie/legislation/food_legislation.html

[41] Regulation 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, [2002] OJ L31/1.

[42] European Communities (General Food Law) Regulations 2007 (as amended), S.I. No 747/2007.

[43] European Communities (Labelling, Presentation and Advertising of Foodstuffs) Regulations 2002, S.I. No 424/2008.

[44] European Community (Food and Feed Hygiene) Regulations 2009, S.I. No 312/2010.

[45] Council Regulation 834/2007/EC on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91, [2007] OJ L189/1.

[46] European Communities (Organic Farming) Regulations 2004, S.I. No 698/2007.

legislation imposes the obligation.[47] However, it could be argued that they are common sense and are only guiding/directing principles, rather than rules that require a specific result, and therefore that they should be applied in interpreting relevant law.

As it stands these three principles are obligatory to apply as a result of EU law, where relevant. Although dualist in nature, Ireland recognises the special position of EU law, e.g. by allowing for ministerial regulations to be created that may trump legislative acts where required by EU law.[48] From the point of view of the EU, there is an obligation upon the Member States to incorporate and implement EU law effectively and to give it primacy above national law. The principle of supremacy/primacy, the duty of loyalty, the need for effectiveness in the EU and other tenets of EU law all lead to the situation where: if there is relevant EU law, Irish law must be read in light of it and, in appropriate circumstances, set aside.[49] The principles of prevention, precaution and proportionality are fundamental principles within the EU, as supported by their presence in the Treaty on the Functioning of the EU (TFEU) and in the case-law of the Court of Justice of the EU (CJEU).[50] Furthermore, although the TFEU emphasizes the role of prevention and precaution in relation to environmental protection, Regulation 178/2002 (the General Food Law)[51] clearly applies all three principles in the context of food and feed regarding threats to

[47] E.g. Section 52 of the Environmental Protection Agency Act, 1992 includes a requirement for the EPA to 'have regard to the need for precaution' but this only applies to the potentially harmful effect of emissions where there are 'reasonable grounds for believing that such emissions could cause significant environmental pollution' rather than human health/food law independently.

[48] Article 29.4.6 of the Irish Constitution (Bunreacht na hÉireann) provides that nothing in the Irish Constitution 'invalidates laws enacted, acts done or measures adopted by the State' that are necessary as members of the EU. Furthermore, each Treaty amendment has involved a constitutional referendum and thereby constitutional amendment. Consequently, it makes a constitutional challenge to resulting EU law extremely challenging, e.g. B de Witte, 'Direct Effect, Primacy, and the Nature of the Legal Order' in P Craig and G de Búrca (eds), *The Evolution of EU law*, (2nd edn, OUP, 2011) at 355.

[49] E.g. cases such as Case C-26/62 *Van Gend en Loos v Nederlandse Administratie der Belastingen* [1963] ECR 1; Case C-6/64 *Costa v ENEL* [1964] ECR 585; Case C-11/70 *Internationale Handelsgesellschaft v Einfuhr- und Vorratstelle fűr Getreide und Futtermittel* [1970] ECR 1125; and C-106/77 Simmenthal II [1978] ECR 629. Also e.g. de Witte, *ibid*; and N Foster, *EU Law Directions*, (3rd edn, OUP, 2012) at Chapter 5.

[50] E.g. Article 191 TFEU contains prevention and precaution in relation to the environment (but with mention of health and Article 11 requires environmental protection components to be integrated across EU law); Case T-147/00 *Laboratoires Servier v Commission* [2003] ECR II-85, para 52; Joined Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00, & T-141/00, *Artegodan GmbH v. Commission* [2002] ECR 11–4945, para 184; and Case C-132/03 *Ministero della Salute v Coordinamento delle Associazioni per la Difesa dell'Ambiente e dei Diritti degli Utenti e dei Consumatori (Codacons)* [2005] ECR I-416, para 35. Proportionality has long been accepted as a general principle of EU law: Case C-11/70 *Internationale Handelsgesellschaft* [1970] ECR 1125.

[51] Article 7 deals with the precautionary principle directly, whilst prevention can be seen `throughout the Regulation. Similarly proportion is reflected in various elements of the Regulation, including regarding the precautionary principle and in relation to national enforcement of the Regulation.

health. Consequently, any Irish law implementing EU law should be interpreted in light of these principles where relevant, but without necessarily necessitating a specific outcome.[52]

There is a wide range of relevant common law principles and doctrines, e.g. proportionality, prevention, *Rylands v Fletcher*,[53] trespass, nuisance, negligence, and so forth, which can have an impact. Much of the common law is relevant specifically to the issue of liability, as discussed below.

Authorisations and Restrictions of GMOs in Ireland

Within the EU and therefore Ireland, prior authorisation is required for both cultivation and use of GMOs as food/feed. The authorisation procedure for GM food and feed is outlined below, with a brief mention of some of the main differences with the authorisation procedure for GM cultivation under Directive 2001/18. Once authorised, the GMOs may be sold, used or cultivated in accordance with their authorisation across the entirety of the EU and Member States may not impose restrictions except in accordance with EU law. However, they may only be used or marketed in accordance with the authorisation received. There is no threshold for products regarding the maximum level of GMOs in them (or regarding the use of GMOs in producing them).

From 2004 until April 2007, under Article 47 of Regulation 1829/2003, GM foods and ingredients that were in the authorisation process and which had had a favourable safety assessment by the relevant EU scientific committee were permitted at levels no greater than 0.5 %.[54] However, now there is a zero tolerance approach to unauthorized GM food and ingredients. Any presence of unauthorised GMOs requires that the product be removed from the market. The product can be destroyed or, if imported, it could technically be returned to the originating State (presuming that this is outside the EU). However, as noted above Regulation 619/2011 establishes a new tolerance for limited presence (up to 0.1 %) of unauthorised GMOs in feed in specific circumstances.

[52] A Doyle and T Carney, 'Precaution and Prevention: Giving Effect to Article 130r Without Direct Effect' (1999) 8 European Environmental Law Review 44.

[53] *Rylands v Fletcher* (1868) LR 3 HL 330.

[54] Regulation 641/2004 dealt with implementing Regulation 1829/2003 and provided for transitional measures regarding GMOs that had received favourable risk evaluations.

Authorisation Process[55]

EU law determines the admission of GMOs in food production, including GM food and feed. The authorisation process commences at a national level, but the risk assessment and decision are effectively made at the EU level rather than national. Any food or feed receiving authorisation at the EU level is automatically authorised within all the Member States, including Ireland.

Regulation 1829/2003 on GM food and feed is the primary piece of legislation. It applies to GMOs for food and feed use, food and feed containing GMOs, and food and feed produced from or containing ingredients produced from GMOs. Regulation 1829/2003 provides for a single authorisation procedure for these products within the EU.[56] Articles 5 and 17 detail the application process for food and feed respectively, both of which include aspects regarding release into the environment also. Articles 4 and 16 require authorisation for any of these products, but also impose negative obligations in relation to the nature of food and feed respectively. In particular, both must not '*have adverse effects on human health, animal health or the environment*', '*mislead the consumer*' or '*differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.*' Furthermore, feed must not *'harm or mislead the consumer by impairing the distinctive features of the animal products'*.

In Ireland, Regulation 1829/2003 is implemented by the 2004 GM Feed Regulations and by the 2013 GM Food Regulations. The Irish law mirrors the EU legislation, by providing that only those products that comply with the 2003 Regulations can be placed on the market or used.[57]

Regulation 1829/2003 requires that the notifier provide appropriate information[58] to the national competent authority (in Ireland, this is the Food Safety Authority of Ireland (FSAI) for GM food and the Minister of Agriculture, Food and the Marine for GM feed).[59] The requisite information is detailed in Regulation 1829/2003 and includes data relating to its safety and monitoring. The competent authority is to acknowledge receipt in writing within 14 days and transmit the information to EFSA, which carries out an evaluation of the risks and provides an Opinion. EFSA may request national competent authorities to carry out risk assessments. However, where the authorisation relates to GMOs or food or feed containing

[55] On the regulation of GMOs in Ireland and the EU, see generally: M Lee, *EU Regulation of GMOs-Law and Decision Making for a new Technology* (Edward Elgar, 2008), although somewhat amended since then.

[56] E.g. Article 27 provides for an application relating to both GM food and feed simultaneously. Articles 5 and 17 provide for consideration of environmental and other issues arising from deliberate release, facilitating authorization under Part C of the Deliberate Release Directive, i.e. authorization for cultivation.

[57] Article 4 of the 2004 GM Feed Regulations. Article 6 of the 2013 GM Food Regulations.

[58] In other words, the authorisation system is greatly reliant upon the information and initial assessment provided by the notifiers themselves.

[59] Article 3 of the 2004 GM Feed Regulations and Articles 5 and 17 of Regulation 1829/2003.

or consisting of GMOs that are to be used for cultivation also, then an environmental risk assessment under Directive 2001/18/EC must be carried out by the national competent authority (the EPA in Ireland).[60] Furthermore, the relevant competent authorities are to be consulted. Member States and the public (including NGOs) have the opportunity to make comments in relation to the application and the risk assessments. The risk assessment by EFSA and by any national competent authorities are to be based on both the prevention and precautionary principles, therefore dealing with potential threats that arise in cases of scientific uncertainty.[61]

Following EFSA's Opinion and any comments by the public, the European Commission creates a draft decision in light of the assessment. Any deviations from EFSA's Opinion must be justified. The relevant comitology procedure applies, leading to a Standing committee of national experts considering and voting upon the draft decision. The current procedure is that of the examination procedure under Article 5 of Regulation 182/2011.[62] If the Standing Committee does not achieve a qualified majority, the matter is passed to the Appeal Committee (until recently, this would have passed to the Council instead). If the Appeal Committee does not arrive at a qualified majority, then the Commission may choose to adopt the proposal or not. If authorisation is granted, it is for 10 years and the operator must apply for a renewal at the end of this period.

Alternatively, for purely cultivation purposes, authorisation can still be sought under Directive 2001/18 and therefore in Ireland under the 2003 Deliberate Release Regulations. Under Article 26 of the Regulations, consent from a competent authority of a Member State is required (in Ireland, the EPA). The authorisation procedure in Article 29 for cultivation is similar to that of Regulation 1829/2003, but with a somewhat greater role for the initial competent authority, which will make an evaluation of the dossier and prepare an assessment report with accompanying recommendations regarding authorisation. Also, unlike with GM food and feed, an application relating to cultivation does not necessarily have to be assessed by EFSA-this will depend on whether there are concerns regarding human or animal health. However, very few applications have been made under Directive 2001/18 directly since the possibility has arisen for making a single application under Regulation 1829/2003.

Under Article 41 of the 2003 Deliberate Release Regulations, the notifier must comply with any conditions attached to the consent. Similarly, Article 21 of Regulation 1829/2003 imposes similar obligations in relation to GM food and feed. Furthermore, if authorisation is received for any GMOs, there will also be general conditions imposed upon them regarding traceability, monitoring, notification of

[60] Articles 6 and 18 of Regulation 1829/2003.

[61] Although Regulation 1829/2003 does not expressly refer to these principles, Article 1 notes that the objective of the Regulation is to be achieved 'in accordance with the general principles' in Regulation 178/2002.

[62] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, [2011] OJ L55/13.

new information and so forth, either at an EU level or nationally. These may be under GM laws[63] or horizontal laws, such as those relating to labelling or food law.

If authorised, then it is EU-wide authorisation and Member States cannot apply a blanket ban to cultivation/use of the GMOs. Although there is currently no cultivation of GM crops in Ireland and there are a number of self-declared GM-free areas (not legally binding), there is currently no existing official *moratorium* or invocation of relevant safeguard clauses in Ireland in relation to any GM food, feed or crops. However, EU law permits the Member States, including Ireland, to impose restrictions via safeguard clauses, coexistence measures and shortly an opt-out clause where in accordance with the relevant criteria.[64] There is also the possibility for voluntary actions by non-State bodies.

Safeguard Clauses

Safeguard clauses provide an additional, post-authorisation method of protection for the environment and human health, typically where new scientific evidence indicates a relevant risk. The main safeguard provisions are found with the TFEU, the GMO laws and Regulation 178/2002. The legislation provides for safeguard measures at the EU level also, but the ones examined are those by Member States and therefore those that are open to Ireland.

Applicable to all GMOs are Article 114(4) and (5) TFEU, which relate to the possibility of maintaining or introducing unilateral national measures respectively. Of these, Article 114(4) will be easier to justify, but is highly unlikely to be relevant in Ireland as there are no relevant existing restrictions. Article 114(5) requires that Member States demonstrate: '*new scientific evidence relating to the protection of the environment or working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure'*. The provision therefore excludes health protection. Furthermore, the criteria are cumulative, i.e. the evidence must (i) be 'new' and 'scientific', (ii) relate to environmental protection or the working environment, (iii) be 'specific' **and** (iv) arise after the harmonising measure's adoption. The two most difficult criteria to fulfil are those of 'newness' and specificity.

Regarding cultivation, Article 23 of Directive 2001/18 allows for unilateral safeguard measures where: '*as a result of new or additional information . . . affecting the environmental risk assessment . . . on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO . . . constitutes a risk*

[63] E.g. Articles 30, 41, 42 and 43 of the 2003 Deliberate Release Regulations. The GM Feed and GM Food Regulations do not impose such requirements directly, but they refer to the obligations in Regulations 1829/2003 and 1830/2003. Articles 5, 12, 13, 17, 24 and 25 of Regulation 1829/2003 are relevant. Similarly, Articles 4, 5 and 8 of Regulation 1830/2003 are particularly relevant.

[64] M Dobbs, 'Co-existence of GMOs in the EU – A Veritable Choice for Whom?' in M Cardwell and J McMahon (eds) *Research Handbook on EU Agriculture Law*, (Edward Elgar 2015).

to human health or the environment.' As with Article 114(5) TFEU, there is a requirement of newness,[65] but there is no requirement of specificity and the provision extends to the protection of human health also. Although the CJEU has expressly declared that such clauses reflect the precautionary principle[66] and therefore they should also be interpreted in light of this principle, restrictive interpretations are clearly visible in particular regarding the criterion of 'newness'.[67]

Also relevant to cultivation, Article 18 of Directive 2002/53/EC[68] provides for safeguard measures in relation to seeds. This provision is of more limited scope, but is relevant to human health and the environment and does not impose requirements regarding either newness or specificity. This does not mean that the requirement that the threat be 'established' or that there be 'imminent danger' will be interpreted liberally however.[69]

In the context of food and feed, Article 34 of Regulation 1829/2003 provides for emergency measures in accordance with Regulation 178/2002: '*Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002.*' Article 53 of Regulation 178/2002 mirrors this provision, whilst Article 54 essentially permits the Member States (including Ireland) to take temporary measures if the Commission has not acted in accordance with Article 53. France attempted to avail of Article 34 of Regulation 1829/2003 recently in *Monsanto (France)*,[70] but the CJEU applied it strictly with no reference to the precautionary principle[71] and emphasized the (EU) centralized nature of the risk assessment and management.[72]

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[65] This is debatable if one examines the provision in the various official languages of the EU, due to the syntax and also the specific words chosen.

[66] Case C-6/99 *Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others*, [2000] ECR I-1651, para. 44.

[67] Joined Cases T-366/03 and T-235/04 *Land Oberösterreich and Republic of Austria v Commission*, [2005] ECR II-4005; Case C-121/07 *Commission v France* [2008] ECR I-9159*;* and the Opinion of Advocate General Mazák of 5 June 2008 in Case C-121/07 *Commission v France* at pt. 44. See also Dobbs (n74) at 1354–5.

[68] Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, [2002] OJ L193/1. Article 16(2) of the Directive also provides scope for unilateral national measures along the same lines as Article 18.

[69] Commission Decision 2006/10/EC of 10 January 2006 concerning the provisional prohibition in Greece of the marketing of seeds of maize hybrids with the genetic modification MON 810 inscribed in the common catalogue of varieties of agricultural plant species, pursuant to Directive 2002/53/EC, [2006] OJ L7/27.

[70] Joined Cases C-58/10 to C-68/10 *Monsanto SAS and Others v Ministre de l'Agriculture et de la Pêche*, [2011]ECR I-7763.

[71] M Weimer, 'The Right to Adopt Post-Market Restrictions of Genetically Modified Crops in the EU - A Shift from De-Centralised Multi-Level to Centralised Governance in the Case of GM Foods' (2012) 3 EJRR 445.

[72] *Monsanto (France)* (n70), para 78.

As exceptions and limitations on harmonisation, where the situation has already undergone a risk assessment, these provisions are generally tightly interpreted at the EU level. The Member States in effect must demonstrate that, despite the prior authorisation procedure and conditions imposed, the existing situation is insufficient to protect the relevant objective. Indeed, although the application of Article 18 of Directive 2002/53/EC has been accepted,[73] the use of Article 23 of Directive 2001/18 has never been approved yet by EFSA or the Commission.[74] Generally, it will be very challenging for Member States, including Ireland, to rely effectively upon the safeguard clauses.[75]

In order to facilitate the use of these safeguard measures, the EU and Irish laws provide for monitoring of the GMOs and notification by the operator to the competent authority in case of any new evidence that might be relevant to a risk assessment and threats to the environment or human health. As of yet, Ireland has never availed of the safeguard clauses in relation to authorised GMOs. If the situation arises where they wish to, a further difficulty will be in choosing which safeguard clause to rely upon as multiple clauses may be relevant and it is unclear as to which takes priority.[76] In reality, Member States are likely to rely upon as many as are relevant and offer the best chances of success.

In the case of discovery of unauthorised GMOs, Ireland of course may and indeed must take appropriate unilateral actions to rectify the situation.

Coexistence Measures

Article 26a of Directive 2001/18 (inserted by Regulation 1829/2003) allows for Member States to *'take appropriate measures to avoid the unintended presence of GMOs in other products'*, i.e. to facilitate the coexistence of GM crops alongside non-GM crops, reflecting the principle of subsidiarity. This in effect recognises the difficulties with avoiding admixture of crops in particular and the impact of local

[73] Commission Decision 2006/335 of 8 May 2006 authorising the Republic of Poland to prohibit on its territory the use of 16 genetically modified varieties of maize with the genetic modification MON810 listed in the Common catalogue of varieties of agricultural plant species, pursuant to Council Directive 2002/53/EC [2006] OJ L124/26.

[74] Nonetheless, the previous comitology procedure made the lifting of national prohibitions based on Article 23 of Directive 2001/18 impossible in practice for the Commission, as the Council were able to block proposals to lift the prohibitions. See M Dobbs, 'Legalising General Prohibitions on Cultivation of Genetically Modified Organisms' (2010) 11 GLJ 1347 at 1354–6. The Commission did succeed in lifting prohibitions relating to GM food and feed, as well as Greece's prohibition regarding seeds (Decision 2006/10/EC).

[75] E.g. N. de Sadeleer, 'Procedures for Derogations from the Principle of Approximation of Laws under Article 95 EC' (2003) CMLRev 40, 889; and F.M. Fleurke, 'What Use for Article 95 (5)? An Analysis of *Land Oberösterreich* and *Republic of Austria v Commission*' (2008) 20 JEL 267.

[76] See e.g. Article 5(5) of Regulation 1829/2003; Article 12(1) of Directive 2001/18; and *Monsanto (France)* (n70).

conditions. In Ireland, it is the role of the Department of Agriculture, Food and the Marine to develop national coexistence measures. These measures may be *ex ante*, i.e. ones that aim to prevent or limit admixture, or be *ex post*, i.e. ones that deal with liability should admixture arise. Thus, national measures can include for example buffer zones or special procedures regarding cleaning equipment. These may of course also be provided for in the conditions in individual licences/consents.

Although within the competence of the Member States, the Commission nonetheless has a role laid out for it in Article 26a(2) of the Directive and as such has provided guidance documents in relation to coexistence, as well as taking a number of other steps that could be seen to reduce the freedom or discretion of the Member States.[77] The most recent guidance document was the 2010 Commission Recommendation on Coexistence.[78] This is a soft law document and consequently not binding upon the Member States, although it is likely to be of highly influential value upon Member States[79] and in any case before the CJEU.[80] The main aspect within the Commission's Recommendation is the focus upon economic impact and the viability of the alternative crop, with some preferential treatment of non-GM crops, i.e. coexistence measures should be created so as to avoid disproportionate economic impact upon non-GM crop farmers. The focus is upon the labelling thresholds and whether, for example, products will need to be labelled as GM or not be able to be labelled as organic as a result of admixture. Consequently, the goal is not to avoid admixture entirely, but to avoid it to the extent that it would have an economic impact.[81] In contrast with the 2003 Recommendation it replaced,[82] the 2010 Recommendation recognises the particularly sensitive position of organic producers and even that some farmers may wish to aim at zero admixture.[83]

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[77] E.g. the creation of a Co-existence Network (Decision 2005/463/EC, [2005] OJ L164/50) and a Co-existence Bureau (M Lee, 'Multi-Level Governance of GMOs in the EU: ambiguity and hierarchy', in L Bodiguel & M Cardwell (eds.), *The Regulation of GMOs: Comparative Approaches* (OUP, 2010)).

[78] Commission Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, [2010] OJ C200/1. For further on the 2010 Recommendation see M Dobbs, 'Excluding Coexistence of GMOs? The Impact of the EU Commission's 2010 Recommendation on Coexistence' (2011) 20 RECIEL 180.

[79] Thus, Ireland considered the previous 2003 Recommendation in developing their report on coexistence (page ix of the Report on coexistence, available at: http://www.agriculture.gov.ie/media/migration/publications/2005/coexistenceofgmandnon-gmcropsinireland/report.pdf).

[80] Dobbs (n78).

[81] The very logic of coexistence seems somewhat faulty considering that admixture will occur and undoubtedly increase over time. Generally coexistence measures will favour one agri-type over another: L Levidow and K Boschert, *Coexistence or contradiction? GM crops versus alternative agricultures in Europe?*, 39 GEOFORUM 174, 174, 181, 187 (2008).

[82] Commission Recommendation 2003/556 of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming, [2003] OJ L189/36.

[83] 2010 Co-existence Recommendation, [2010] OJ C200/1, Guidelines, Section 2.4.

In Ireland in 2003, an interdepartmental working group was set up within the Department and various groups were consulted,[84] leading to a report in 2005.[85] In doing so, Ireland considered the existing 2003 Commission Recommendation on Coexistence, amongst other factors.[86] The resulting recommendations[87] were to entail mandatory and voluntary guidelines that were primarily of an *ex ante* nature, but also did consider the issue of economic liability. Some of the key recommendations related to prior approval from the Department and to buffer zones. However, currently they remain as non-binding recommendations, which have been left sit without any statutory implementation. Considering the lack of cultivation in Ireland, it is not surprising that not much effort is apparent in reviving these recommendations. As it stands, the EPA can of course consult these recommendations when they are considering an application for a consent/licence, but it would be beneficial to have a clear-cut position in relation to coexistence measures. It should be borne in mind that even national coexistence measures will need to be flexible, as conditions vary even across such a small country as Ireland.

The main challenge in relation to coexistence in Ireland in the future is the significant practical challenge in preventing admixture and specifically outcrossing in the long-term if there are different agri-types cultivated of genetically compatible crops. As there are currently no commercially available bio-confinement measures to definitively prevent admixture,[88] coexistence measures will inevitably involve some form of buffer zones/segregation.[89] The measures will necessarily favour one agri-type or another and, combined with the 'domino effect' will lead to it being incredibly difficult to maintain coexistence in the long-term.[90] This is escalated in Ireland by how small the island is and the potential for cross-border issues with Northern Ireland. Interestingly, an amendment has been made to Article 26a that will come into force in 2017, ***requiring*** Member States to take appropriate measures where necessary to avoid the possibility of cross-border contamination – this would impose duties upon both the United Kingdom and Ireland in relation to avoiding any such possible issues.[91]

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[84] See generally http://www.agriculture.gov.ie/gm_coexistence/.

[85] Available at: http://www.agriculture.gov.ie/media/migration/publications/2005/coexistenceofgmandnon-gmcropsinireland/report.pdf.

[86] E.g. pages 1–2 of the report; and the Foreword and Executive Summary available at: http://www.agriculture.gov.ie/media/migration/publications/2005/coexistenceofgmandnon-gmcropsinireland/introduction.pdf.

[87] Xiii-xv of the Executive summary.

[88] E Glon 'A geographical approach to the European policy for the co-existence of GMO and non-GMO crops' in Y Bertheau (ed), *Genetically Modified and non-Genetically Modified Supply Chains: Co-Existence and Traceability* (Wiley 2012), at 570.

[89] J Corti-Varela, 'Coexistence of genetically modified, conventional and organic products in the European market: state of the art report' (2010) 1 European Journal of Risk Regulation 71.

[90] Dobbs (n78).

[91] Article 1 of Directive 2015/412, C. Macauley, 'GM crop-growing banned in Northern Ireland', 21 September 2015, BBC News, http://www.bbc.co.uk/news/world-europe-34316778.

As Northern Ireland has just announced that it will prohibit the cultivation of genetically modified crops under the new opt-out provision (see below), this increases the significance and urgency for Ireland of determining how it will manage cross-border issues. In considering coexistence measures, it should be recalled that any measures must be proportional, comply generally with EU law (including the internal market rules) and comply with WTO law[92] – whilst some might only breach the TBT Agreement and be relatively easy to justify, if Ireland were to create for instance an island-wide exclusion zone as necessary to prevent admixture, this would then breach the GATT as a quantitative restriction and would need to be justified under Article XX of GATT. As the basis for coexistence measures in Article 26a differ from those justifications available under GATT, this would mean that Irish measures to that level of severity could only comply with either EU or WTO law but not both.

Opt-outs

In 2010, the Commission, following a request by a number of States including Ireland,[93] proposed a Regulation to amend Directive 2001/18 and create an opt-out clause for Member States in relation to GM cultivation (proposed Article 26b).[94] Following difficult negotiations,[95] a Greek compromise[96] was accepted by the Council in June 2014.[97] A revised version of this proposal was adopted by the Parliament in January 2015, which the Council undertook to approve.[98] This has led to Directive 2015/412, which came into force in April 2015 and inserted both Article

[92] J Scott 'European regulation of GMOS and the WTO' (2002–3) 9 Columbia Journal of European Law 213.

[93] Note Submitted by Austrian Delegation, Genetically Modified Organisms – A Way Forward (June 25, 2009), http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2011226%202009%20REV%202

[94] *Proposal for a Regulation amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory*, COM (2010) 375 final (July 13, 2010).

[95] E.g. *Progress Report*, 6 June 2012, 10883/1/12 REV 1: http://register.consilium.europa.eu/doc/srv?l=EN&t=PDF&gc=true&sc=false&f=ST%2010883%202012%20REV%201, 5; and M Weimer, 'Risk regulation, GMOs, and the challenges to deliberation in EU governance: politicization and scientification as co-producing trends' (2014) Amsterdam Centre for European Law and Governance Working Paper Series 2014–03.

[96] Annex to Council of the EU, *Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory – political agreement*, note to Council, Brussels, 28 May 2014 (10271/14).

[97] Council of the EU, Press Release, 12 June 2014 (10415/14): http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/143178.pdf

[98] *European Parliament legislative resolution of 13 January 2015 on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or*

26b and Article 26c into Directive 2001/18 and also amended the coexistence regime in relation to cross-border issues as noted above.

The essential components to the new opt-out procedure found in Article 26b involve two stages, whereby if Ireland wishes they may first 'demand' a geographical adjustment (limitation) from a notifier. This stage is flexible, in so much as Ireland need not provide any reasons for their request and the notifier can agree to amend their notification for (re-)authorisation with the relevant geographical limitation – indeed failure to respond during the relevant period will lead to the notification automatically being so adjusted. However, Ireland must make this request during the (re-)authorisation period,[99] which creates time restraints that may be significant[100] and also indicates that this is on a product-by-product basis.

Under the Greek compromise, generally only if the notifier refused the limitation could that same Member State avail of the second stage and notify a restriction based upon an objective justification.[101] Thus, Ireland could only have imposed a restriction using the proposed opt-out if they had previously requested and been refused a geographical limitation. However, although Recital 13 of Directive 2015/412 includes an expectation that most restrictions or prohibitions would be implemented at the (re-)authorisation stage, the agreed text now removes this procedural step and allows for Member States to avail of the opt-out at any stage. Furthermore, Article 26b provides for the restriction to apply to individual GMOs or a group of related GMOs, increasing the flexibility again.

However, if any Member State, including Ireland, wishes to opt-out and impose a restriction unilaterally it must be objectively justified. Article 26b(3) includes a non-exhaustive list of potential objective justifications, including environmental policy objectives, but expressly excludes the possibility of conflicting with the environmental risk assessment carried out in the authorisation process. This can be understood on the basis that the EU considers its regime to provide sufficient protection and also in light of the result of the Biotech Dispute and the reasoning of the Dispute Panel.[102] The Dispute Panel considered that the existing national prohibitions were in breach of the SPS Agreement (despite the EU attempting to avail of

prohibit the cultivation of genetically modified organisms (GMOs) in their territory (10972/3/2014 – C8-0145/2014 – 2010/0208(COD)).

[99] There is a transitional period allowing for requests regarding currently authorised GMOs, but any restrictions must not affect authorized crops that are already planted.

[100] EPEC, 'Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) 1829/2003, and the placing on the market of GMOs as or in products under Directive 2001/18/EC', Final Report to DG SANCO, March 2011: http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo_cultivation_report_en.pdf, 96–7 and 106–7.

[101] Exceptions were possible where objective circumstances excused earlier inaction and any restriction did not detrimentally affect crops already planted legally.

[102] COM(2010) 380 final at 6 noted that the 2010 Coexistence Recommendation and the proposed Article 26b were to provide the Member States with more flexibility, with the consequence that they might not avail of the safeguard clauses in circumstances that the Commission and EFSA considered inappropriate.

Article 5.7 of the SPS Agreement and precautionary principle in their arguments) and required that any restrictions for health or environmental reasons be based upon sufficiently thorough risk assessments.[103] However, Ireland might be able to justify any potential restrictions on the basis of objective justifications such as public morality, which is an acceptable justification within WTO law also (Article XX of GATT). It would thereby avoid the SPS Agreement being raised and the treatment of this justification may be sufficiently flexible to allow prohibitions to be accepted by the Dispute Panel and Appellate Board as proportionate.[104]

It is quite likely that Ireland will avail of Article 26b, at least for some of the country, but would attempt to avoid conflict over the proportionality of restrictions by requesting geographical limitations from the notifier first.

Voluntary Measures

The EU prohibition on impeding access to the market is one that applies to Member States and their bodies. For the main part, individuals and corporations are free to make their own choices, in so much as there is a practical choice available. Consequently, farmers may choose to cultivate authorised GM crops or use authorised GM feed or not. Similarly, retailers may choose to stock GM products, producers may choose to use GM ingredients and consumers may choose to purchase GM products - or not. It is open to any of these parties not to cultivate or use in any other form authorised GMOs and hence one of the reasons why labelling, monitoring and traceability is so important.

This possibility is exemplified within Europe by the existence of the GM-Free Network.[105] Many areas within Ireland are part of this Network. However, if Ireland itself were to step in and even promote GM-free crops or produce, it would likely be in breach of general EU internal market law and Ireland would then have to justify it under EU law.[106]

It bears noting how insecure these measures are, as they are dependent on other parties, e.g. on farmers, suppliers and retailers. In the context in particular of farming, the practical challenges for coexistence demonstrate how difficult it is to maintain a GM-Free area if there is not a unanimous approach. Furthermore, the level of GMOs in feed make it economically and practically challenging to use solely non-GM feed – as reflected in the change to permit minimal presence of unauthorised GM feed in some circumstances.

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[103] See Section VIII Conclusions and Recommendations of the Panel's Report (n32).

[104] On the objective justifications under the proposed Article 26b, see: Dobbs (n74).

[105] 'Charter of the Regions and Local Authorities of Europe on the Subject of Coexistence of Genetically Modified Crops with Traditional and Organic Farming' (Florence, 2005).

[106] N de Sadeleer, *EU Environmental Law and the Internal Market* (OUP 2014), 259–300.

Finally, it is important to emphasize: whilst anyone may take voluntary measure and there are safeguard clauses applicable to all GMOs, coexistence measures and the opt-out are purely available for cultivation rather than for GM food or feed.

Regulation of the Regime

Although the authorisation process occurs for all GMOs predominately at the EU level, the Member States play the central role in relation to monitoring and enforcement within their own territories.[107] The EU laws also provide for the Member States to create offences and penalties, with the requirement that these be effective, proportionate and dissuasive in nature.[108]

In Ireland the EU laws have been implemented by the abovementioned Regulations, with some reliance on other legislation such as the EPA Act, 1992 and the FSAI Act, 1998. Together they indicate the relevant competent authorities and enforcement mechanisms. For each regime, there exists a range of enforcement mechanisms, including powers of the competent authorities, the possibility of administrative sanctions and the possibility of regulatory offences and therefore prosecution. These will vary depending on the focus, i.e. whether GM crops, food or feed.

This section outlines the relevant competent authorities and how they operate. Some of the administrative sanctions and regulatory offences are detailed in the section below on liability.

Field Trials and Cultivation

This area is predominately regulated by the Deliberate Release Regulations along with the EPA Act, 1992, and bearing in mind Regulation 1830/2003 regarding traceability and labelling. The EPA plays the main role in considering authorisations, monitoring and initially enforcing the area. However, the Department of Agriculture, Food and the Marine plays a role regarding GM seeds and also regarding the overall approach to co-existence.

Part V of the Deliberate Release Regulations provides for the enforcement and regulation of the regime by the EPA. They can monitor or carry out inspections (Article 66), impose notices (Article 60) and prosecute relevant offences under these Regulations or relating to the EPA Act, 1992 (Article 58).

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[107] E.g. Articles 14 and 26 of Regulation 1829/2003 and Article 9 of Regulation 1830/2003. As a Directive, Directive 2001/18 must generally be implemented by the Member States. Hence it is understandable that the Irish implementing Regulations are more detailed than those implementing Regulations 1829/2003 and 1830/2003, which are directly applicable.

[108] E.g. Article 33 of Directive 2001/18, Article 45 of Regulation 1829/2003 and Article 11 of Regulation 1830/2003.

GM Food

GM food law in Ireland is primarily regulated under the FSAI Act, 1998 and the GM Foodstuffs Regulations. Under both pieces of legislation, it is the FSAI who plays the primary role in implementing, monitoring and enforcing GM food law. Provision is made once more for inspections, sampling, enforcement notices and so forth.[109] As with cultivation, the Director of Public Prosecutions (DPP) may play a role in the case of indictable offences. Some of the offences available are detailed in the section on liability below.

GM Feed

GM feed law in Ireland is primarily regulated under the GM Feeding Stuffs Regulations, with the primary role for the Department of Agriculture, Food and the Marine. There are similar powers regarding monitoring and enforcement for authorised persons (Article 6). Articles 9 and 10 provide respectively for prosecutions of offences and on the spot fines.

Generally, the sampling and inspection powers are not reserved to those products labelled as GM, as this would be ineffective. Consequently, the food surveys carried out by the FSAI can be seen to analyse foods not labelled as GM for the purpose of seeing whether they comply with GM food law and labelling laws generally.[110] As shall be seen below, in the case of any indictable offence (primarily regarding GM food or crops, but not feed), the DPP can take prosecutions before the High Court. It is open to third parties, including NGOs, obviously to participate in enforcement, e.g. by informing the relevant competent authority of any discrepancies such as where NGOs test products that are supposedly non-GM and they transpire to contain GMOs to the point that they require labelling or even potentially are unauthorised within the EU. This can be an incredibly important role, especially due to the limited availability of resources for the State bodies.

As the rules are based in EU law, if Ireland or its authorities fail to implement or enforce the law effectively, legal challenges may be brought even before the CJEU, e.g. if an operator considers that Ireland is imposing an illegal restriction upon their products.[111] Furthermore, the Commission, as 'watchdog' of EU law, may also bring cases against the Member States including Ireland for breach of EU law *via* Article 258 TFEU,[112] although this raises political and practical challenges of its own.

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[109] Part IV of the FSAI, Act 1998 and Part 4 of the 2013 GM Food Regulations.

[110] Available at: http://www.fsai.ie/enforcement_audit/monitoring/surveillance/genetically_modified_food_surveillance.html

[111] E.g. *via Francovich* liability: C-6/90 & 9/90 *Francovich v Italy* [1991] ECR I-5537.

[112] E.g. B Jack, 'Enforcing Member State Compliance with EU Environmental Law: A Critical Evaluation of the Use of Financial Penalties' (2010) 23:1 JEL 73.

Labelling

The main relevant legislation is Regulation 1830/2003 (supplemented by Regulation 1829/2003 on GM food and feed), which requires that GM food and feed is traceable and labelled throughout the food chain until the last moment on the market. As well as allowing for consumers to be informed, the combination of traceability and labelling enables for the withdrawal of products where for example new scientific evidence indicates risks to the environment or health. Generally speaking, labelling as GM is required of any products containing or consisting of GMOs or produced from GMOs, whether there is any GM DNA present or not.[113] However, if the presence of authorised GMOs is adventitious or technically unavoidable and below a threshold of currently 0.9 %, then even though there are GMOs present the products do not require labelling.[114]

The EU GM labelling and tracing rules were eventually implemented in Ireland by the 2013 GM Food Regulations (these Regulations implemented both Regulations 1829/2003 and 1830/2003 in relation to food) and the 2004 GM Feed Regulations. The Irish regulations require that such labelling (or, where a label is impractical, an accompanying notice) contains words such as 'genetically modified', 'this product contains genetically modified organisms' or 'product produced from GM (name of organism)'.[115] Paralleling EU law, the Irish Regulations do not require that food or feed be labelled as GM, if the only GMOs present are authorised in the EU, under 0.9 % and either adventitious or technically unavoidable.[116] Parts 2, 3 and 4 of the GM Food Regulations provide for offences where the requirements of the Regulations are not met, including those regarding traceability and labelling. Articles 8 and 9 of the GM Feed Regulations provide for offences, including those regarding traceability and labelling.[117]

Neither the Irish nor EU GM Regulations deal with labelling products as GM-free or organic. However Article 9 of Regulation 834/2007/EC prohibits the use of GMOs and products produced from or by GMOs in organic production. Consequently, if produce is labelled as organic, it cannot contain or be produced from GMOs. This is directly applicable in Ireland and the Regulation is also implemented by 2004 Organic Farming Regulations[118] as amended.

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[113] However, labelling is not required of products made with the use of GMOs, e.g. meat from animals fed GM feed.

[114] E.g. Articles 4(7), 4(8), 5(4) and 7(2) of Regulation 1830/2003, in conjunction with Articles 12(2) and 24(2) of Regulation 1829/2003.

[115] E.g. Articles 7 and 11 of the 2013 GM Food Regulations.

[116] E.g. Articles 7 and 12 of the 2013 GM Food Regulations.

[117] Article 8 provides that failure to comply with the provisions of Regulations 1829/2003 or Regulation 1830/2003 is an offence.

[118] European Communities (Organic Farming) Regulations 2004, S.I. 112/2004.

Currently there is no legislation dealing expressly with GM-free labelling at EU level or nationally. However, the EU Commission is investigating the possibility of a EU-wide voluntary scheme for GM-free labelling.[119]

Furthermore, these rules work in conjunction with other labelling rules, e.g. those regarding fraudulent or misleading labels and also with Regulation 1830/2003 and Regulation 767/2009[120] regarding the general labelling rules provided for the marketing of feed.

Labelling Fraud

There is no law that relates directly to labelling fraud in the case of GMOs. However, the general rule under Irish and EU law is that labelling must be accurate and not false or misleading, including where it relates to GMOs. Products mislabelled must be withdrawn from the market and potentially destroyed.

This issue is mainly controlled by consumer protection law, e.g. the Consumer Protection Act 2007 that replaced the Consumer Information Act 1978 and also transposed the EU Directive 2005/29/EC on Unfair Commercial Practices.[121] This Act protects consumers against false or misleading claims about goods (including therefore about GMOs). The main aspects relevant to GMOs and labelling are the prohibitions on unfair commercial practices and on misleading commercial practices.[122] Under the Act it is an offence to make false claims about the characteristics of a product.[123] Offenders are liable to criminal prosecutions, including by the National Consumer Agency (NCA) that was established by the Act. Article 47 provides for criminal liability for relevant offences, including '*on a first conviction on indictment for any such offence, to a fine not exceeding €60,000 or imprisonment for a term not exceeding 18 months or both'*, with the potential for both increased penalties for subsequent convictions and for daily penalties for continuing offences. Furthermore, Article 74(2) provides for any aggrieved parties to have a right of action for damages, including exemplary damages. There is also a name and shame aspect, with Article 86 providing for publication by the NCA of lists of those fined or convicted.

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[119] Consultation letter from the UK Food Standards Agency, 31 January 2013: http://www.food.gov.uk/sites/default/files/multimedia/pdfs/eu-gm-free-labelling-wales.pdf

[120] Regulation 767/2009/EC on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC, [2009] OJ L229/1.

[121] Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council, [2005] OJ L149/22.

[122] E.g. Article 42 as expanded upon in Article 43.

[123] E.g. Article 47 in conjunction with Articles 42 and 43.

The 2002 Food Labelling Regulations[124] implement Directive 2001/13/EC[125] amongst other EU laws and also require that labelling be clear, unambiguous and not mislead the consumer to a material degree. If the labelling is misleading, it is an offence and the relevant person may be subject to fines or prosecution.[126] However, Article 19 of the 2002 Food Labelling Regulations only provides for penalties of up to €3,000 and/or 3 months of imprisonment upon summary conviction and Article 20 provides for a defence including due diligence.[127] Nonetheless, the issue must also be remedied, e.g. the label amended or the product confiscated, withdrawn or destroyed.[128] Although, Directive 2001/13 was replaced by Regulation 1169/2011/EU[129] since 13 December 2014, the law in relation to misleading labelling remains much the same, as Article 7 of Regulation 1169/2011 still prohibits food information from being misleading.

Importantly, Article 7 of Regulation 1169/2011 considers that labelling can be misleading if it suggests '*that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients'*. Therefore, not only is it misleading to label something as GM-free if it contains GMOs (even below the threshold), but it is also misleading if there is not a version of the foodstuff that could be labelled GM in accordance with EU rules, i.e. organic food (no other organic food could derive from GMOs as prohibited in the production of organic food), food derived from animals such as meat or dairy products (no GM animals authorised in the EU and food derived from animals fed GM feed is not considered GM under EU law) and products for which there is no GM counterpart, e.g. fruit and peanuts. Yet it is permissible to have labels such as 'from animals fed non-GM feed', provided it is accurate. Similarly, 'GM-free' maize would be acceptable if accurate, as there is GM maize authorised in the EU.

Similarly, Article 21 of the 2009 Food and Feed Hygiene Regulations[130] makes it an offence to, by act or omission, mislead or attempt to mislead consumers in contravention of Article 16 of Regulation 178/2002 (general principles of food law). However, in contrast with the general food labelling regulations above, Article 30 of

[124] European Communities (Labelling, Presentation and Advertising of Foodstuffs) Regulations, S.I. No 483/2002.

[125] Directive 2001/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, [2001] OJ L109/29.

[126] Article 4 of the 2002 Food Labelling Regulations.

[127] Article 20 of the 2002 Food Labelling Regulations.

[128] See further: http://www.fsai.ie/legislation/food_legislation/labelling_presentation_advertising_foodstuffs/general_labelling_provisions.html

[129] Regulation 1169/2011/EU on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, [2011] OJ L304/18.

[130] EC (Food and Feed Hygiene) Regulations 2009, S.I. No 432/2009.

the 2009 Regulations provides also for penalties to include, on conviction on indictment, fines of up to €250,000 and/or 3 years in prison. Consequently, to mislead or attempt to mislead consumers in relation to either food or feed will be an offence and the person will be liable to prosecution, fines and imprisonment as detailed.

Regulation 767/2009 on feed provides for a similar approach to Directive 2001/13 and Regulation 1169/2011. In particular Article 11 deals with misleading labelling. These Regulations are directly applicable in Ireland, without need for implementing legislation technically. However, on a practical basis, they require legislation to provide for the enforcement of the provisions, e.g. through providing for offences and penalties as required by Article 31 of Regulation 767/2009. Ireland has yet to develop new legislation to implement them specifically, but the 2009 Food and Feed Hygiene Regulations implementing other EU legislation may suffice for the purposes. To suffice, the 2009 Regulations would have to be read sufficiently broadly to encompass the elements within Article 11 of Regulation 767/2009. This is a feasible interpretation, as the specifics in Regulation 767/2009 are merely examples of what may be involved in misleading the user.

There is also the Sale of Good and Supply of Services Act 1980, which amends the Sale of Goods Act 1893 and provides extra protection for consumers. Here, the goods much be as described[131] (amongst other requirements) and, as an implied condition, if they are not as described, the purchaser may rescind the contract and/or claim damages for losses incurred. Furthermore, if a person enters a contract based on a misrepresentation, then they may be able to rescind the contract, without alleging fraud.[132] In either case, the defendant may be liable for losses to the plaintiff flowing from the lack of congruency between the description/representation and the product.[133] The scope is limited however to protecting consumers.

Also of relevance, there is a Code of Standards for Advertising, Promotional and Direct Marketing, which is regulated by the independent self-regulatory body Advertising Standards Authority of Ireland (ASAI).[134] According to the ASAI, all commercial marketing communications must be 'legal, decent, honest and truthful'.[135] Any communications in breach must be withdrawn (following the report of an independent committee) or amended. The media play a key role here in refusing to publish advertisements that do not conform with the Code. Reports, naming and shaming, are made publicly available. If a member of the ASAI does not accept the decisions, they can be disciplined, including fines and suspension of membership. The Code does not cover labels on individual projects, but is relevant to for example broader advertisements of products by a producer or by a retailer.

[131] S.10 of the 1980 Act, replacing s.13 of the 1893 Act.

[132] See S.44 of the 1980 Act.

[133] S. 45 of the 1980 Act relates to misrepresentations, although contracting parties may provide for fair and reasonable limitations: s.46 of the 1980 Act.

[134] http://www.asai.ie/ASAI%20CODEBOOK_REVISED_2012.pdf

[135] *Ibid*, at 3.

Following the beef/horse controversy in Ireland and the EU in 2013, the FSAI established a Food Fraud Task Force. Its role is to gather information and communicate with other relevant persons/bodies in Ireland or internationally[136] and is intended to work in conjunction with the Rapid Alert System for Food and Feed (RASFF), thereby making it more efficient. RASFF is a European notification system (led by the European Commission), which is designed to facilitate the swift exchange of information between Member States in relation to hazards to health posed by food or feed. In light of the horsemeat incident, the Commission is intending to expand RASFF to include food fraud (currently it technically only applies where there is a serious risk to health). The European Commission have also recommended a number of significant changes at the EU level, but which still need to be approved by the other institutions. The proposed Official Controls Regulation[137] would increase the deterrence in relation to food fraud, e.g. by increasing the fines, monitoring and unannounced spot checks.

If the matter is very serious in relation to the fraud, Article 6 of the Criminal Justice (Theft and Fraud Offences) Act 2001 might be applicable. Article 6 (1) provides that 'A person who dishonestly, with the intention of making a gain for himself or herself or another, or of causing loss to another, by any deception induces another to do or refrain from doing an act is guilty of an offence.' Offenders are liable under Article 6(2) on *'conviction on indictment to a fine or imprisonment for term not exceeding 5 years or both.'*

Overall, there is a range of legislation that impacts upon the labelling of GM and non-GM products. Together they effectively result in a system where any product resulting from a GM process must typically be labelled as GM, unless purely deriving from an animal fed GM feed or where adventitious or technically unavoidable and under 0.9 %. There is no harmonised GM free label as of yet and Ireland would likely find itself in murky waters if it sponsored any itself, as comparable to promoting GM-free regions. However, retailers and NGOs or other non-State entities may label non-GM produce as GM free, provided that it is accurate and there is a GM counterpart available lawfully in Ireland. If the required labelling is missing or any labelling is misleading or fraudulent, then there are a range of offences and consequences for those responsible. Together the traceability and labelling rules in EU

[136] FSAI Newsletter, July-August, available at http://www.fsai.ie/uploadedFiles/News_Centre/Newsletters/Newsletters_Listing/FSAI_News_v14i4.pdf at 4; and https://www.fsai.ie/enforcement_audit/food_fraud_task_force.html

[137] Proposal for a Regulation of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [....]/2013 [Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation), COM(2013) 265 final.

and Irish law a support a system that is protective of consumer health and choice in particular. It is arguable however that consumer choice is not effective where exceptions exist, as not truly reflecting the facts. It is further undermined by the fact that, as admixture occurs and increases, products may be put on the market that unknowingly contain GMOs.[138]

Liability

As with other aspects relating to GMOs, there is no legislation dealing specifically with liability regarding GMOs in Ireland. However both case-law and legislation (relating to GMOs and more general legislation) provide for civil, administrative and criminal sanctions. As shall be seen, typically private individuals will only be able to take actions where their persons or property have been detrimentally affected, where the relevant criteria are fulfilled, and these will be civil or criminal actions.[139] Competent authorities however may impose relevant administrative sanctions/conditions (typically not involving the need to appear before court) or take actions before the courts. These actions will typically be criminal (frequently for breach of a regulatory offence), but in some circumstances civil litigation may be appropriate. The regulatory offences may lead on from the administrative sanctions, e.g. failure to comply with an administrative sanction or condition may constitute an offence that can be prosecuted, or for breach of a consent condition, or for breach of some more general statutory requirement.

Generally speaking, the burden of proof is on the plaintiff for each element in establishing liability and the standard is that of the balance of probabilities in civil law, whereas in criminal law it is that of beyond reasonable doubt. There is little criminal law that relates to GMOs, other than the destruction of property (e.g. of GM crops by protesters), fraud (dealt with in the context of labelling) and the commission of regulatory offences (e.g. the growing of crops without authorisation, the sale of unauthorised GM food/feed or failure to comply with licence conditions or administrative sanctions). In the case of regulatory offences, frequently there will be strict liability offences, which eases the burden on the prosecutor.

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[138] Case C-132/03 *Ministero della Salute* v *Coordinamento delle Associazioni per la Difesa dell'Ambiente e dei Diritti Degli Utenti e dei Consumatori (Codacons)* [2005] ECR I-4167, Opinion of Advocate General Léger of 3 March 2005, paras 81–2: 'the average consumer who is reasonably well-informed and reasonably observant and circumspect' might now expect a low level of presence of GMOs in all foods as the 'contamination of the environment by GMOs is a well-known phenomenon'.

[139] Besides civil and criminal actions, they can also take a judicial review of for instance an administrative decision to grant a cultivation licence. They could also take an action against Ireland for State liability under EU law if the circumstances were relevant, e.g. failure to implement EU law on time and effectively, where this resulted in a loss to the plaintiff. This could be relevant for instance to failure to implement the Environmental Liability Directive in relation to damage caused between April 2007 and April 2009 (although it would prove challenging to demonstrate how the plaintiff was harmed as a result).

As noted above, labelling issues may result in liability, whether civil or criminal, as well as in administrative sanctions (e.g. the removal of the product from the market and enforcement notices).

Civil Liability

Raymond Friel wrote a chapter on economic liability relating to GMOs (specifically regarding economic liability flowing from GM crops, but of relevance to GM food and feed also) in Ireland in 2008[140] and little has changed since, with the exception of the 2008 Environmental Liability Regulations,[141] which entered into force on 1 April 2009. There is the possibility for economic liability under statute or under common law. However, the most likely base for economic liability currently is under tort law, as coexistence measures have not been implemented and the 2008 Environmental Liability Regulations are quite limited in scope. Regarding both cultivation and GM food and feed, there is the limited possibility of product liability (see the following sub-section). However, this is unlikely to be of much use.

The EU's Environmental Liability Directive[142] is an important tool for environmental protection, but was of limited use in Ireland until it was implemented by the 2008 Environmental Liability Regulations.[143] The relevant competent authority is the EPA and they may require preventative or remedial work, require that the costs be paid, request injunctions from the High Court or initiate proceedings for regulatory offences (see below). The Regulations encompass environmental damage or the imminent threat of environmental damage caused by activities under the Deliberate Release Regulations.[144] Article 17 also specifically provides for the economic liability of the operator causing the environmental damage (or imminent threat thereof) in relation to preventative or remedial measures.[145] However the scope of 'environmental damage' is severely limited[146] and does not encompass general damage to the environment or damage to land that is not under special protection or does not involve a risk to human health. Furthermore, Article 3(3) states that: *'Without prejudice to an enactment or rule of law that confers a right on a*

[140] R Friel, 'Economic Loss Caused by GMOs in Ireland', in BA Kock (ed.), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops* (Springer, 2008).

[141] European Communities (Environmental Liability) Regulations 2008, S.I. 547/2008.

[142] Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, [2004] OJ L143/56.

[143] For example see G Winter, JH Jans, R Macrory and L Krämer, 'Weighing up the EC Environmental Liability Directive', (2008) 20:2 JEL 163 at 186–9.

[144] Article 3 and Schedule 2 of the 2008 Regulations.

[145] Also of relevance, Article 18 provides for joint and several liability.

[146] Explanation by the EPA, available at: http://www.epa.ie/enforcement/liab/. This reflects a combination of the definitions in Regulation 2 and the scope in Regulation 3.

person who suffers loss or harm to seek relief by way of damages in respect of same, these Regulations do not confer such a right on a person who suffers loss or harm as a result of environmental damage or imminent threat of environmental damage.' Consequently, although the Regulations provide for economic liability of operators, this is not a mechanism targeted towards landowners whose property has been damaged or made less valuable. The action is one for the EPA to take regarding environmental damage. It is questionable what use this has in relation to for instance admixture.

The Deliberate Release, GM Food and GM Feed Regulations do not provide expressly for actions for economic liability by individuals. However, as Friel notes, if they met the criteria whereby *'the plaintiff must be (i) a member of the class that the statutory provision was designed to protect and (ii) have suffered harm over and above that incurred by other members of that class'*,[147] then civil actions for breach of statutory duty would be available. However, this does not appear to be the case for any of the GM legislation.

To incur liability under contract law, the vendor (and specifically therefore not third parties earlier in the food chain) must have breached either a statutory duty (e.g. those in the Sale of Goods and Supply of Services Act 1980 regarding being fit for purpose, of merchantable quality or as described, which protect consumers) or a contractual term. This typically will be strict liability and will allow for the contract to be rescinded and/or claims for compensation depending on the circumstances. This is unlikely to be of much use for the consumer (as they for instance are unlikely to be testing the DNA of the products or whether the exact nutritional contents described are present), but contractual terms may be of relevance to retailers or parties that are purchasing large quantities to use for the purpose of their business, e.g. farmers or those involved in food processing.

There is also the potential for civil liability for damage to individuals' property (including crops) or persons through common law doctrines in tort law,[148] e.g. *via* the law of trespass, negligence, nuisance or *Rylands v Fletcher*.[149] For all of these actions bar trespass,[150] damage/harm to the plaintiff's property or person will be required that is caused[151] by ('but for')[152] the defendant's actions. Other contributing

[147] Friel (n140), at 280. This is based on *M'Daid v Milford Rural District* [1919] 2 *The Irish Reports* 1.

[148] For further information generally on the law of torts in Ireland see for example: B McMahon and W Binchy, *Law of Torts* (4th edn, Tottel Publishing, 2013); and P Ward, *Tort Law in Ireland*, (Kluwer Law International, 2010).

[149] Friel (n140), examines the use of negligence, nuisance and the rule in *Rylands v Fletcher* in relation to the cultivation of GMOs. See also: the section on Ireland in V Wilcox, 'Summaries of the Country Reports', in Koch (n140).

[150] However, the quantum of liability for trespass will be minimal unless there has been damage inflicted. Furthermore, for trespass, presence of the GMO on the plaintiff's property will be required.

[151] See Friel (n140), at 280–5 regarding causality for negligence, nuisance and *Rylands v Fletcher.* Also see Chapter 2 of McMahon and Binchy (n148).

[152] E.g. *Corrigan v HSE* [2011] IEHC 43.

factors do not prevent liability of the defendant but there may be contributory negligence by the plaintiff, which will reduce the liability of the defendant partially or entirely. Furthermore a *novus actus interveniens* will act as a defence, as it involves an act of a third party or nature that is sufficient to break the causal link-it becomes the legal cause of the injury.[153]

The main difficulty in establishing causality in relation to admixture would be where there are multiple potential sources but it is not definite which one is the actual source, e.g. where a bakery uses flour from multiple supposedly non-GM sources or where there are multiple GM crops near a compatible non-GM crop. In such a circumstances, it may be possible to rely upon s. 11.3 of the Civil Liability Act 1961 in order to consider all relevant parties as concurrent wrongdoers.[154] Alternatively it might be feasible to apply the *res ipsa loquitur* doctrine, whereby the burden of proof is reversed for this element, on the basis that the information relevant to the matter is in the hands of the defendant(s). To apply this doctrine the item potentially causing the damage must be in the control of the defendant and the events in issue would not have happened in the ordinary course of things without an act of negligence.[155] This was raised regarding the issue of pollution in the case of *Hanrahan v Merck Sharp & Dohme*.[156] However Hench J for the majority considered that the doctrine was to protect the plaintiff in the situation where the information was 'peculiarly within the range of the defendant's capacity of proof' and to apply the normal burden would be 'palpably unfair' to the plaintiff.[157] He continued that 'mere difficulty of proof' was insufficient to shift the burden of proof.[158] However this was in relation to a strict liability matter and Henchy J noted that the argument 'would be more sustainable' if it related to negligence instead, which leaves the door somewhat ajar in the case of negligence if not for other heads of action. It should also be noted that plaintiffs may request information from defendants, e.g. through discovery or notices for particulars as occurred in this case, which may facilitate establishing causality.

A further general requirement for actions in tort is that the damage must not be too remote. The general approach is that the damage must be within a range of injuries that are reasonably foreseeable for actions based in negligence[159] and nuisance.[160] However, the exact nature and extent of damage does not have to be reasonably foreseeable. In strict liability cases, including where *Rylands v Fletcher*

[153] *Power v Bedford Motors* [1959] IR 391; and *Murray v Miller and Brady*, 14th November 2001, Roscommon Circuit Court, Judge McMahon. Also see McMahon and Binchy (n148), at 115–7.

[154] Friel (n140), at 285.

[155] Friel (n140), at 283.

[156] *Hanrahan v Merck Sharp & Dohme (Ireland) Ltd* [1988] IESC I; [1988] ILRM 629.

[157] *Ibid*, at 20. This departs from the traditional approach to the doctrine.

[158] *Ibid*, at 21.

[159] See Chapter 3 of McMahon and Binchy (n148); *The Wagon Mound (No1)* [1961] AC 388; and *Condon v CIE et al*, unreported judgment of Barrington J in the High Court, 16 November 1988.

[160] *The Wagon Mount (No2)* [1967] AC 617 and *Wall v Morrissey* [1969] IR 10 extend the test of foreseeability in relation to remoteness of damage from negligence to the area of nuisance.

applies and trespass, it is considered that the damage merely must result as a direct consequence of the relevant actions by the defendant, which is broader in scope than the test of foreseeability.[161] Once it is considered that the damages are not too remote, the 'egg-shell skull' rule will also apply, whereby the defendant must take the plaintiff as they find them,[162] e.g. if reasonably foreseeable that a farmer growing relevant crops would be harmed, but the farmer suffers even greater harm because they grow organic crops, then the defendant can be held liable for the more severe damages.

Negligence

The predominate tortious action is that of negligence, based on the 'neighbour principle' in *Donoghue v Stevenson* [1932] AC 562. Where it is reasonably foreseeable that the absence of reasonable care by the defendant towards the plaintiff would result in an injury to the plaintiff or their property, then there is a duty of reasonable care upon the plaintiff to avoid such a scenario. Where this duty is breached leading to such harm to the plaintiff, the defendant will be liable for negligence (fault-based). This can apply to producers or retailers vis-à-vis consumers, but it will be necessary to establish each cumulative element. A relatively recent case in Ireland, which upholds a variation of the neighbour principle is that of *Glencar Exploration*,[163] which focuses on (1) the proximity of the parties, (2) the foreseeability of the damage and (3) whether it is just and reasonable to impose a duty of care.[164]

An action based on negligence relating to injury to the person will prove very challenging in the case of GM food or feed, regarding their nature as GM, especially considering that all authorised GMOs in Ireland have been assessed for safety. Regarding damage to property, this is most likely to occur through admixture and specifically admixture relating to GM crops (it is somewhat easier to regulate non-agricultural products, e.g. as wildlife are less likely to facilitate admixture). As admixture has the real potential to impact upon labelling requirements for products, including crops, which can have a knock on value upon their commercial value, this could be a significant impact. Friel considers that such a loss may not be reasonably foreseeable, unless there is an organic farmer smack bang in the middle of fields of similar GM crops,[165] but even conventional farmers (and individuals in the retail chain further down the line) will be affected in relation to labelling, unless the exception applies (<0.9 % and technically unavoidable or adventitious). Consequently, it would appear that such harm would be reasonably foreseeable and

[161] McMahon and Binchy (n148), at 145.

[162] E.g. *Burke v John Paul & Co Ltd*, [1967] IR 277.

[163] *Glencar Exploration p.l.c. v Mayo County Council* [2002] 1 ILRM 481.

[164] This contrasts with the previous approach in *Ward v McMaster* [1988] IR 337 at 349, which considered in place of 3) the absence of any compelling exception based upon public policy, i.e. it was only if such a compelling existed that a duty would not be imposed.

[165] Friel (n140), at 282.

caused by any negligent acts of the defendant that led to admixture. Thus, the main likelihood for liability based on negligence would be through admixture with crops on a plaintiff's property, leading to economic loss.

As well as being fault based, there are also defences of statutory authority, the *novus actus interveniens* and contributory negligence. Consequently, if feasible, the plaintiff is more likely to attempt to base their claim on nuisance, *Rylands v Fletcher*, trespass or statutory liability.

Nuisance[166]

Although there are two types of nuisance, public nuisance is of very limited relevance here. Private nuisance is not actionable *per se* (i.e. damages must be demonstrated that are caused by the nuisance), but does involve a form of strict liability unlike negligence.[167] However, private nuisance relates to land solely and consequently is relevant to cultivation and possibly feed, but not to food. The nuisance must cause damage that involves physical injury to land, substantial interference with the enjoyment of land, or an interference with servitudes where the disturbance constitutes a substantial interference with the plaintiff's rights.[168] Therefore, only those with a proprietary interest in the land will be able to sue. Furthermore, personal injury is not included. Defence may be provided by statutory authority. There may also be a partial defence through contributory negligence by the plaintiff. If the nuisance has continued for 20+ years, there may be a defence of prescription.

Rylands v Fletcher[169]

This is similar to nuisance and could be subsumed into it or alternatively a variation of negligence (the area is in flux and quite confused). It requires that the defendant bring something dangerous on to land owned/controlled/occupied by defendant, where it is put to a 'non-natural use' and from where it escapes on to land owned/controlled/occupied by the plaintiff where it causes harm. Defences include acts of God/nature, statutory authority and in limited circumstances an act of a stranger. The last applies where it is a deliberate act of a third party, who for instance is not an employee or invitee of the defendant. The fault of the plaintiff may act as a total defence or partial, i.e. basically contributory negligence.

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[166] Chapter 24 of McMahon and Binchy (n148).

[167] *Cambridge Water Co Ltd v Eastern Counties Leather plc* [1994] 1 All ER 53. Nonetheless, there is a move to using reasonableness, so the action is no longer based purely on strict based liability.

[168] McMahon and Binchy (n148) at 990.

[169] See generally Chapter 25 of McMahon and Binchy (n148).

Trespass[170]

Trespass encompasses entering or remaining on land, or bringing/placing things on to land, without permission. It is actionable *per se*, i.e. damage need not be established in order to bring an action. Furthermore, the burden in effect is upon the defendant to demonstrate that the incursion was neither negligent nor intentional. However, to recover compensation, it will be necessary in practice to demonstrate damages. Relevant defences include consent, lawful authority and necessity.

The actions under nuisance, *Rylands v Fletcher*, and trespass are of limited applicability regarding GMOs and especially GM food and feed. Negligence remains the head of action of broadest relevance. However, causation will prove substantially challenging in bringing any action, except in the clearest of cases.

Where successful, there are two types of remedies available for the actions in tort.[171] The first is that of damages and in particular monetary compensation for damages incurred,[172] in order to put the plaintiff back in the position that they would have been otherwise-including lost profits to a limited extent. The second is an injunction. Injunctions are possible prior to damage (need to show irreparable damage will result if injunction not granted) or indeed where there is continuing damage. An interlocutory or interim injunction is unlikely, since prior authorisation is received and there are conditions applied to limit/avoid the chance of admixture between crops or other products. Consequently it would be very challenging to demonstrate that there would otherwise be irreparable damage. Furthermore, if the threat relates to personal injury and therefore the claim is that the GMO is unsafe, then evidence would need to be established that would contradict that relied upon in the initial authorisation-a difficult challenge, especially since the authorisation is EU wide and restrictions on authorisations must be in compliance with EU law. In the case where such evidence was actually accepted by the Irish courts (or where the issue related to unauthorised GMOs), then one would expect that a nationwide approach would be taken by the relevant competent authority instead-withdrawing the relevant product(s) from circulation, informing the EU Commission and Member States of the facts, availing of RASFF and/or implementing the safeguard clause procedure. However, where there has been some admixture and the issue relates to damage to property, then both damages and an injunction may be appropriate. The first will compensate for the initial damage, whereas the injunction could prevent further admixture and therefore further damage. Thus, the main practical use of an injunction would be where admixture occurs and affects the value of the plaintiff's property as a result.

[170] See generally Chapter 23 of McMahon and Binchy (n148).

[171] See Chapters 44 and 45 of McMahon and Binchy (n148).

[172] There is the possibility of other damages, e.g. punitive or exemplary damages.

Product Liability for Defective Products

Again, there is no specific liability regarding GM products. There is general product liability provided for in the case-law and in legislation, but unless the GM food makes the consumer sick or harms them in some other way, this will not be of much relevance. This is as the defective product must (a) be defective and (b) harm the individuals or their property rather than merely represent the harm itself. A defective product in the case of GM food/feed could be one that does not have a relevant beneficial trait or one that poses a threat to human or animal health if consumed as ordinarily. Statutory liability for defective products focuses on their dangerous nature, whereas the common law does not impose such a restriction as the common law is not specifically focused upon product liability. Instead, it is merely that the common law relating to tort and contract are applied to the scenario where there is a defective product at the centre of the case (similarly other statutes do not focus specifically upon defective products).

The main piece of legislation is Liability for Defective Products Act 1991, which implemented Council Directive 85/374/EC[173] on Products Liability and makes producers (and secondarily other individuals involved in the retail chain) liable for injury or damage caused wholly or partly by defective products/components. In contrast with actions under negligence, liability is strict based, but the causal link between the defect and the harm must still be demonstrated on the balance of probabilities. The Act provides a remedy for those who have been injured (through either physical damage to property or personal injury) by defective products in a non-commercial capacity to recover against the producer of that item. Section 1.1 defines products as '[a]ll movables, even where the movables are incorporated into other movables or into immovables' and they include primary agricultural products since Directive 1999/34/EC[174] due to concerns over vCJD/BSE. Section 5.1 provides that *'a product is defective if it fails to provide the safety which a person is entitled to expect, taking all circumstances into account, including—(a) the presentation of the product, (b) the use to which it could reasonably be expected that the product would be put, and (c) the time when the product was put into circulation'* Thus the focus of the Act is upon safety and the defect must be dangerous in the context. However the most serious limitation is found within Section 6. This provides for defences and includes crucially where the defect is due to compliance with an EU standard or law, or that the state of scientific and technical knowledge at the time the product was put into circulation by the defendant was not such as to enable the existence of the defect to be discovered. Consequently, it makes incredibly difficult

[173] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, [1985] OJ L210/29.

[174] Directive 1999/34/EC amending Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, [1999] OJ L 141/20.

for producers to be held liable for defective products if they are complying with the original authorisations.

Administrative Requirements/Sanctions

These are a tool to avoid or minimise damage or contravention of a statute, or possible remedy a damage that has already occurred. It is inappropriate to speak of causation, damage, burden of proof etc in relation to the administrative sanctions themselves. Instead, the relevant competent authority (or possibly voluntary body such as the ASAI) imposes fresh requirements upon the operator, which must be complied with. Where they are not complied with, further actions may be possible, e.g. prosecution for failure to comply with a notice.[175] Typically liability will be strict.

Examples of administrative sanctions include:

The possibility to impose directions or requirements regarding preventative or remedial measures under the Environmental Liability Regulations (the Regulations also provide for having these enforced via injunctions-Article 22);
The possibility to impose an on the spot fine in Article 10 of the 2004 GM Feed Regulations;
The use of notices under Article 60 of the Deliberate Release Regulations;
The possibility of seizure, removal or detention of foodstuffs under Article 21 of the 2013 GM Food Regulations; and
The use of 'improvement notices', 'closure orders' or 'prohibition orders' under Sections 52, 53 and 54 of the FSAI Act, 1998.[176]

Administrative sanctions are an important regulatory management tool and in effect a stepping-stone. They facilitate the national competent authorities in encouraging compliance through less severe (and costly) measures than an outright prosecution, but with the knowledge that failure to comply with the measures may lead to further actions.

Criminal Law (Primarily Regulatory Offences)

There is no criminal law specific to GMOs, but there is of course the possibility that general criminal law, statute or common law, will apply, e.g. fraud, trespass, theft and so on. If so, typically speaking the offences will be fault based, unlike most regulatory offences. However there are numerous offences that can be applied

[175] As in the case of Article 8 of the 2004 GM Feed Regulations.

[176] It is possible to bring appeals against the closure and prohibition orders.

within environmental law, health law/food law and beyond. The main criminal offences are found within the statutes on GMOs or other key environmental/health statutes, relate to mislabelling (above) or involve the breach of authorisation conditions.

Actions will typically be open to the relevant competent authority or public prosecutor, i.e. the EPA (for cultivation), the FSAI (for food), the Department of Agriculture, Food and the Marine (for feed) and the DPP (for offences regarding any GMOs considered serious enough to be prosecuted upon indictment). Generally speaking, there will be the possibility to take a criminal action against the defendant for either a summary offence (seen as less serious, before the District Courts and with much lower fines and terms of imprisonment where relevant) or an indictable offence (seen as more serious, before the High Courts with a jury and with the potential for large fines and long prison sentences).

Cultivation

The GM Deliberate Release Regulations were made pursuant to the Environmental Protection Agency Act, 1992, which has significant consequences in relation to liability. Section 8 (1) of the EPA Act provides that: *'Any person who contravenes any provision of this Act or of any regulation made under this Act or of any order made under this Act or of any notice served under this Act shall be guilty of an offence.'*[177] Section 9 continues by providing for liability following summary and indictable convictions, with penalties including *'a fine not exceeding £10,000,000 or to imprisonment for a term not exceeding ten years or, at the discretion of the court, to both such fine and such imprisonment.'* Section 9(3) also provides for daily penalties of up to £100,000 where the defendant continues to contravene the provision following conviction.[178] Thus, any breach of any provision of the Deliberate Release Regulations counts as an offence susceptible to the above penalties and is based on strict liability.

Furthermore, the 2008 Environmental Liability Regulations provide for a number of offences, including causing environmental damage, not taking the necessary steps to avoid known imminent threats, interfering with investigations and not taking appropriate preventative or remedial measures as directed/required. Most of the offences are found in Articles 7, 8, 9, 10 and 12 and are dealt with under Article 24(1) and (2). Article 24 provides for penalties including *'a fine not exceeding €500,000 or to imprisonment for a term not exceeding 3 years or both'*, but also provides for a defence where *'the person took all reasonable steps to avoid the commission of the offence.'*

[177] Section 8(2) provides for the potential liability of bodies corporate.

[178] The amounts here are in Irish pounds and the approximate exchange rate would be £1 to €1.27.

Feed

The 2004 GM Feed Regulations contain a number of offences, e.g. Article 8 provides that:

'*A person who –*

a) *obstructs or otherwise interferes with an authorised officer in the performance of his or duties*,
b) *without lawful excuse, refuses or fails to comply with a request of an authorised officer*,
c) *gives information to an authorised officer that the person knows to be false or misleading in a material respect, or*
d) *fails to comply with the provisions of these Regulations or the EC Regulations shall be guilty of an offence.'*

The duties referred to include those in Article 6 of the Regulations, which involve extensive powers such as inspection, access to documents, detention of products and so forth. Article 8(d) includes offences such as placing an authorised product on the market, failing to comply with consent conditions or breach of labelling requirements. Consequently, in conjunction with the EU Regulations (1829/2003 and 1830/2003) there is a very broad range of offences. Most of these are strict based, but others (provision of false or misleading information) are fault based. Article 9 of the Regulations also provides for bodies corporate to be held liable. However, unlike with cultivation, Article 9 only provides for liability based on summary conviction and 'to a fine not exceeding €3,000 or up to six months imprisonment.' Consequently, the offences do not seem to be taken very seriously, without the option of prosecuting on indictment.

Food

The offences for GM food are wide-ranging, with some included in Article 24 of the 2013 GM Food Regulations, elsewhere in these Regulations, in the EU Regulations and in the FSAI Act, 1998. Some of the more general offences relate to not placing relevant products on the market unless an authorisation is granted in accordance with Regulation 1829/2003 and the conditions are complied with,[179] failure to comply with monitoring and reporting requirements,[180] failure to provide relevant information following authorisation,[181] failure to label appropriately,[182] and failure to

[179] E.g. Article 6(1) and (2) of the 2013 GM Food Regulations.

[180] Article 6(3) of the 2013 GM Food Regulations.

[181] Article 6(4) of the 2013 GM Food Regulations.

[182] Articles 7 and 11 of the 2013 GM Food Regulations. Articles 7(9) and 10(3) also includes an offence of transmitting information that is 'partial, incomplete, false or misleading', which is important as otherwise retailers further downstream will be unable to rely on the data and label their products appropriately.

transmit and maintain the requisite information (including regarding unique identifiers).[183] A defence to the labelling offences is available where the exception detailed above is present (below 0.9 % and adventitious or technically unavoidable).

Article 24 of the 2013 GM Food Regulations includes offences for failure '*to comply with these Regulations'* and generally obstructing authorised officers in the exercise of their powers under the Regulations or knowingly misleading them, thereby creating a wide range of offences. Article 27 provides for liability including '[o] *n conviction on indictment, to a fine not exceeding €500,000, or imprisonment for a term not exceeding 3 years, or both'*, as well as the costs of the FSAI. Article 25 applies this provision equally to a body corporate or a person acting on behalf of a body corporate. Consequently, a similar approach is taken as with GM feed, but with the possibility for far more substantial penalties.

Furthermore, since the 2013 GM Food Regulations are considered food legislation for the purposes of the FSAI Act, 1998,[184] it is important to consider the offences therein also. The FSAI Act, 1998 contains a range of other offences,[185] e.g. those in Section 50 regarding failure to comply with requirements by an authorised officer *'without reasonable excuse'* with potential liability '*on conviction on indictment, to a fine not exceeding £100,000 or to imprisonment for a term not exceeding 12 months or to both'*. Again one finds offences regarding obstructing or knowingly misleading the authorised officers.

Overall regarding the specific regulatory offences, there are a range available that are predominately strict based and generally provide for summary trials and trials on indictment. The choice over which avenue to take is firstly that of the competent authority (typically the EPA, the Department of Agriculture, Food and the Marine or the FSAI), with the DPP then deciding to accept or reject taking the proceedings if the competent authority proposes a prosecution on indictment. However, the Courts may also reject jurisdiction if they believe that the action should be taken at a different level instead.

A related issue would be the potential for non-GM producers to be liable for breach of copyright where there they end up growing GM crops by accident (or on purpose) where admixture occurs. Furthermore, there is the potential for civil or criminal liability in the case where individuals destroy GM products, including crops, as demonstrated in 1999 when 7 GM protesters were brought before the Courts. The protesters were convicted, but their punishments included minimal fines and application of the Probation Act due to 'their firmly held convictions'.[186]

[183] Articles 10 and 13 of the 2013 GM Food Regulations.

[184] Article 15(2) of the 2013 GM Food Regulations.

[185] E.g. Section 51(3) regarding obstructing authorized persons; and Section 56(5) regarding unlawfully removing notices. These are summary offences with relatively minor fines.

[186] The information was previously available at http://archives.tcm.ie/irishexaminer/1999/04/01/ihead.htm (accessed in February 2012). 1 protester was fined £100 and bound over to the peace.

Conclusions

As noted initially, one might expect Ireland as a welfare state that has had a famine historically to have legislated for food security or to have specific fundamental rights regarding the right to food. Similarly, one might expect that Ireland would have been proactive in regulating the area of GMOs and in particular GM cultivation. However, there is no legislation expressly on food security and the legislation specifically focussed on GMOs is of EU origin. The area is highly harmonised, leaving little flexibility to Ireland currently. Ireland's role is predominately in relation to implementation, monitoring and enforcement, with a range of bodies playing important roles.

The regime in place is one that is intended to provide a high level of environmental and health protection, between prior authorisation, traceability, monitoring and safeguard clauses. These are to be interpreted not merely in light of the prevention principle, but also the precautionary principle. This is complemented by the labelling rules and potential for coexistence measures that are to help ensure both producer and consumer choice. In theory therefore one would consider that the system in place would facilitate food security, through ensuring safety, potentially facilitating increases in nutritional quality, increasing competition and allowing effective choice. However, in practice it is questionable how much of an impact GM food has truly had upon this issue in Ireland, considering its low presence, low visibility (despite labelling) and lack of obvious significant nutritional benefits currently. The main link between food security and GMOs in Ireland seems to be that of the authorisation of GM feed (and the new limited tolerance for as yet unauthorised GM feed), considering the significant usage of GMOs in compound feed and the importance of agriculture in Ireland.

From the cultivation side, there is no Irish commercial cultivation of GM crops currently and rarely even field trials – although Teagasc was recently granted permission to carry out field trials, BASF previously considered the costs excessive in order to comply with licence conditions. No Irish coexistence measures have been officially created, but even if they were it is questionable whether coexistence currently is a practical possibility in light of the lack of available bioconfinement mechanisms and the small geographical space available. Furthermore, Ireland has generally positive conditions for agriculture, with little need for GM crops that have been adapted to deal with extreme conditions. Nonetheless, GM crops resistant to specific diseases or other challenges (e.g. if the blight resistant gene use in Amflora potatoes were authorised for potatoes for consumption as feed or food) could improve production, reduce production costs and have a positive impact upon food security. Also, bearing in mind the importance of diversity of crops, food and nutrients, the use of GM crops might permit for GM crops that traditionally only grow in other conditions to be grown in Ireland.[187] Alternatively it might permit for super crops, which have extra nutritional traits present, e.g. as in the case of yellow rice.

[187] Indeed the low level of diversity and high intensity of agricultural production was seen as one of the significant causes of the Irish Famine, e.g. EDG Fraser, 'Food Systems Vulnerability: Using past famines to help understand how food systems may adapt to climate change' (2006) 3:4 Ecological Complexity 328.

Regarding the link with international food security, it is difficult to predict or understand the actual impact, as numerous factors come in to play, e.g. the potential to develop crops here that might be able to be grown in areas with challenging climatic or geographical conditions or with increased rates of production, the possibility that strict rules in the EU (and therefore Ireland) might impact upon trade negatively for Ireland and also for poverty stricken countries with laxer standards, and the possibility that the GMOs might actually have negative effects upon the environment or human health whether through admixture or increased use of specific chemicals (and thereby also the build up of resistance). Clearly, any rules and processes that are relevant to the production of crops, food and feed, will impact in some fashion upon food security. The challenge here for Ireland and others is to determine to what extent GMOs promote and/or endanger food security. Ireland has yet to deal with this concretely, as the EU has dealt with it for the main part and there have been few attempts at cultivation in the State. However Ireland has the potential and need to consider:

1. whether it will opt-out in part or in total from GM cultivation in light of the new Article 26b of Directive 2001/18 (and, if so, upon what grounds);
2. what coexistence measures are appropriate and actually to implement these, unless it opts out entirely;
3. what liability regime, if any, should apply where admixture occurs (as the Environmental Liability Regulations deal exclusively with environmental damage, rather than for instance losses to farmers, and it is questionable whether admixture would be considered environmental damage for the purposes of the Environmental Liability Regulations); and
4. whether a separate liability regime should apply regarding GM food and feed, e.g. where mislabelling occurs.

It also has the option of acting outside of EU law, or at least challenging EU law, e.g. on the basis of a safeguard clause. However, any such challenge would prove extremely difficult to support without relevant new scientific evidence regarding a threat to the environment or human health. In contrast, Ireland also has the option of proactively supporting GMOs, whether in cultivation or in GM food or feed.

As it stands, there is little direct impact of GM production upon food security in Ireland, with GMOs quite tightly regulated. Although loosening of the regulations or the gradual increase of GM food/feed might increase food security, by increasing competition and thereby decreasing the prices, this is not a necessary consequence.

Chapter 6
Genetic Technology and Food Security: Country Report – Italy

Alberto Germanò and Eva Rook Basile

General Information

Use of GMO in Food Production

Italy belongs to the European Union, which has specific rules concerning GMO. Therefore the rules applicable in Italy are exactly the same as those which are in force in the (now) 28 Member States of the Union. This means that our description of the Italian rules can be limited to the essential aspects, so as to avoid overloading the General Reporter with repetitions.

Before addressing the issue of the specific position adopted in 2000 by the Italian Government with regard to a genetically modified Monsanto maize variety, three stages in the evolution of European Union policy on GMOs should be underlined. The first stage was the 1994 Communication of the Commission entitled "Biotechnology and the White Paper on growth, competitiveness and employment", in which the biotechnology sector was considered to be a strategic sector for economic growth. In the second stage, the Opinion of the Economic and Social Committee on the "Proposal for a European Parliament and Council Directive amending Directive 90/220/EEC" of 1998[1] recognised that in 1994 the Community had felt the need "to focus attention primarily on more flexible legislation and

[1] In Guce C 407, 28.12.1998.

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simplified procedures in order to boost new technologies that would have the potential to improve competitiveness and employment", whereas it was now more concerned with reassuring and informing the general public more fully as well as (….) with guaranteeing assessment and monitoring of the immediate and long-term health and environmental risks. The third stage was that of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 – which basically represents the codification of the original Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms – and the subsequent modifications and integrations. This Directive, which aimed to assure an elevated level of consumer protection and environmental protection, was prompted by a sort of "fear" of GMOs, so much so that priority no longer focused on the need "to ensure the safe development of industrial products utilizing GMOs" (6th whereas of Council Directive 90/220/EEC): instead, emphasis was placed on the idea that "the introduction of GMOs into the environment should be carried out according to the 'step by step' principle". This principle stated, for example, that GMOs could be introduced "only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken" (24th whereas of Directive 2001/18). Furthermore, "in order to ensure that the presence of GMOs in products containing, or consisting of, genetically modified organisms is appropriately identified, the words 'this product contains genetically modified organisms' should appear clearly on the label" (40th whereas of Directive 2001/18); additionally, the aforesaid Directive indicates that "the competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment" (47th whereas of Directive 2001/18). The latter approach reflects the reactions of consumers who are unsure whether genetically modified products are safe. In other words, the background to European Union positions reflects concern about the effects of genetically modified foods on human health.

The introduction of European Union rules on GMOs, and their subsequent adoption in Italy, was thus characterised by a step-wise progression of actions over time, in order to take into account the complexity of the problem. First, Directive 90/219/EEC of 23 April 1990 (amended by Directive 98/81 of 26 July 1998, implemented in Italy by Decreto Legislativo No. 206 dated 12 April 2001), on the contained use of genetically modified micro-organisms, established rules to regulate experiments in closed and controlled environments. At a later stage, rules were established to regulate not only field experiments but also the marketing of GMO-derived products, through Council Directive 90/220/EEC of 23 April 1990 (amended by Directive 2001/18 of 12 March 2001, implemented in Italy by Decreto legislativo No. 224 dated 8 July 2003) on the deliberate release into the environment of genetically modified organisms and on the marketing of products obtained with the use of GMOs. Finally, the assessment procedure to evaluate novel foods and novel food ingredients and to ensure proper labelling prior to their placement on the market was introduced by Regulation (EC) n. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, amended, with regard to GMOs, by Regulation (EC) n. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food

and feed, and by Regulation (EC) n. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, and amending Directive 2001/18/EC.

It should be stated as a premise that according to European Union Law, enterprises have the right to grow GM crops because freedom of enterprise is guaranteed by the Treaty which establishes the free circulation of goods, capital, persons and also of enterprises.[2] However, GMO products cannot be introduced onto the European market (a) unless a complex authorisation procedure (at first decentralised[3] but now centralised within the Commission) has been carried out, involving risk analysis, assessment and management, risk management being based on the precautionary principle; and (b) if the GMO products lack the appropriate labelling. In other words, the European Union rejected the claim (advanced by the USA and the OECD) of the substantial equivalence of products obtained by genetic engineering with products resulting from crosses and from natural selection, a claim that was based on the claim that genetically engineered products satisfied the same requirements of form and shape, nutritional substances and organoleptic characteristics as non-GMO products.

Furthermore, within the European Union only the public authorities are officially competent to make a statement concerning the risk and other possible effects of

[2] Freedom of enterprise is also guaranteed by Art. 41 of the Italian Constitution, according to which "economic initiative is free".

[3] Pursuant to Directive 90/220 the standard procedure to be adopted when foodstuffs containing GMOs or constituted by or starting from GMOs were going to be introduced onto the market began with an "application" notified to the national authority that was the competent organ for the market on which the GMO products were to be launched. The notification was followed by an assessment carried out by the competent national authority, and then the application was transmitted to the Commission which, in turn, "sent it on" to the other Member States in order to allow them to put forward their observations. At the end of the 60-day period, if no objections had been raised, the Member State – or the Commission in the case of objections – made a decision with regard to the authorisation. If, due to the absence of objections, it was not necessary for the Commission to make a decision, the Member State that had set the procedure in motion, i.e. the Member State to which the applicant had submitted the request, could not refuse its "written consent" (i.e. the authorisation), but it had to complete the procedure by taking into account its own original favourable evaluation and the positive communication by the Commission (Court of Justice 231 March 2000, C-6/99, *Greenpeace France*). With regard to the *novel foods* regarded as equivalent to conventional foods, Regulation No. 258/97 provided for a simplified procedure: the notification would be sent directly to the Commission, which then transmitted a copy to the Member States and limited itself to publishing, every year, a summary of these notifications in the Official Gazette of the European Union. Once the introduction of the *novel foods* onto the market had been authorised, the foods in question could circulate freely in the Community market; however, Article 23 of Directive 2001/18, as had been the case earlier with Article 12 of Regulation n. 258/97, required what is known as the safeguard clause, on the basis of which "where a Member State (…) has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment" this Member State "may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory". The safeguard clause is also invoked by Article 54 of Regulation No. 178/2002 on food safety and by Article 34 of Regulation No. 1829/2003.

GMOs, and the public authorities are required to make use of the precautionary principle in formulating such statements (in contrast, according to US law this competence is vested in the producers themselves). Additionally, labelling of GMO foodstuffs is compulsory in order to ensure that information concerning biotechnology is transparent and certain.

The concerns voiced by the European Union are fully shared by Italian public opinion, and indeed the Government was the mouthpiece of concerned citizens both in 2000 and in 2013.

In 2000 the Prime Minister's decree dated 4 August 2000 suspended, on a cautionary basis, the marketing and utilisation of three transgenic maize products of the Monsanto Company that had previously been authorised by the European Commission's decisions dated 98/292 and 98/294. These decisions had been issued on the basis of the "notifications" to the Commission by several multinationals (one of which was Monsanto); the decisions concerned the introduction of foodstuffs containing GMO-maize, but according to the scientific opinion expressed by the English Advisory Committee on *novel foods*, GMO maize could be considered "substantially equivalent" to existing food products or ingredients. Regulation No. 258/97 established that in the case of novel foods held to be equivalent to traditional products, the procedure to be followed was the "simplified" version that required only a simple communication to the Commission by the importing company. The Italian Government contested the appropriateness of the procedure, arguing that it would never be possible to assert the "substantial equivalence" between GM maize and traditional maize because the very presence of GMOs – i.e. of something that does not exist in the corresponding traditional product – had the effect, in its own right, of making the maize in question non-equivalent to traditional maize. During the case brought by Monsanto against the Italian Government's decree, the Tribunale Amministrativo Regionale (TAR, i.e. Regional Administrative Court) raised the question, in terms of a preliminary ruling, of whether the Italian decree which stated that the simplified procedure should not, in this case, have been regarded as the correct procedure to follow, was effectively compatible with Community law. The verdict issued by the Court of Justice, in its sentence dated 9 September 2003, case C-236/01, *Monsanto*, asserted that the most likely interpretation according to Community law was that the concept of substantial equivalence does not exclude the hypothesis that new foodstuffs may be considered as substantially equivalent to existing foodstuffs even if "they present differences in composition which are devoid of effects on public health". However, the simplified procedure allowed by Regulation 258/97 could not be taken as meaning that the safety criteria to be respected for foodstuffs could be less rigorous: accordingly, every Member State could challenge the conclusion reached by the Commission, but only after carrying out the appropriate scientific verifications. Therefore, the Court of Justice stated that a Member State's power to make use of the safeguarding clause detailed in Art. 114 of the Treaty on the functioning of the European Union is conditional on the prior undertaking, by the Member State in question, of an assessment of the risk, with reference to the precautionary principle. The Court therefore assigned to the Italian referring court the task of determining whether, in the particular case at hand, the

investigation into the existence of a risk of a danger potentially harmful to human health had been carried out on the basis of the scientific knowledge available at the time of the assessment. The TAR of Lazio, in Verdict No 14477 dated 29 November 2004, accepted Monsanto's appeal but rejected its demand for financial compensation.

In 2013, with the decree dated 12 July, the Italian Ministry of Health, jointly with the Ministry of Agriculture and the Minister of the Environment, issued a ban valid throughout Italy on cultivation of MON810 maize varieties deriving from genetically modified seed "until Community measures are adopted as detailed in Art. 54, section 3, of Regulation 178/2002 and in any case for no longer than eighteen months after the date of the decree". To gain further insight into the Government's position, it should be noted that Sentence C-58/10, dated 8 September 2011, *Monsanto v. Ministre de l'Agriculture et de la Pêche*, issued by the Court of Justice, stated that the Member States cannot suspend or forbid the utilization or marketing of GMOs if the GMOs in question have been authorized pursuant to Regulation 1829/2003, unless the conditions specified in Art. 34 of Regulation No. 1829/2003 hold. The latter Article states that in the presence of new elements, any Member State can adopt emergency measures with regard to the use of GMOs that have already been authorised, by setting in motion the procedure indicated in Art. 53 of Regulation n. 178/2002. Now, with reference to the maize variety MON810, the Italian government underlined several points, as follows: that the authorization for MON180 maize had expired and that the Monsanto Company had asked for the authorization to be renewed; that the Council of the European Union had in the meantime declared there was a need to reinforce the GMO environmental risk assessment procedures; that EFSA had issued new guidelines in 2010, which EFSA had naturally been unable to take into account in 2009 when issuing a decision with regard to the request for renewal of the authorisation; that a new opinion paper issued by EFSA in December 2011 stated that maize BT11 cultivation was found to have a negative impact above all on lepidoptera and that the results of EFSA's investigation should be applied to maize MON810, which produces the same toxin; and that it should therefore be concluded that maize MON810 cultivation could present a severe risk for agrobiodiversity. In addition, the Italian ministerial decree stated that despite EFSA's December 2011 conclusions, no measure for management of the situation had been adopted by the Commission[4]; accordingly – precisely by virtue of Article 53 of Regulation No. 178/2002, and with appropriate respect for the considerations expressed on 2 April 2013 by the Consiglio per la ricerca e la sperimentazione in agricoltura (CRA, i.e. Italian Council for Research and Experiments in Agriculture) and for the opinion of the Istituto Superiore per la

[4] The Italian Ministerial decree states that the French Minister of Agriculture had already, in March 2012, as a cautionary measure, forbidden the sowing of a crop of MON810 maize (but then this decree was nullified by the French *Conseil d'Etat*, 1st August, 2013), and the Commission had not felt any duty to intervene in the form of an extension, modification or repeal of the previous authorisation. Furthermore, the Italian decree mentions the study conducted by the Federal Institute of Technology of Zurich, which claims that the Cry1Ab toxin increases the mortality of ladybird larvae.

Protezione e la Ricerca Ambientale (ISPRA) [Higher Institute for Environmental Protection and Research] dated 30 April 2013 – Italy felt a duty to intervene in a cautionary manner in order to protect the environment and the biodiversity of its own territory.

A number of Italian Regions had already voiced similar concerns and had declared their territories to be GMO-free (on this, see infra, section "Restriction of GMO").

Food Security

In Italy, as elsewhere, the following Regulation is applied and is compulsory: Regulation (EC) n. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. In the European market "food shall not be placed if it is unsafe" (Article 14.1).

Genetically modified foods are not, as a basic principle, in contrast with food security. However, the concerns with regard to possible harmful effects and their influence on human health have induced the European Union to introduce rules requiring a specific authorisation as well as labelling to indicate that a given product has been made with GMOs, before such products can be brought into use and marketed.

Legal Superstructure

Genetic engineering is a twofold phenomenon: it not only represents our most thrilling hopes and aspirations, but also our deepest fears and apprehensions. Genetic engineering can be a source of fear because it involves manipulation of plant or animal DNA: in other words, it induces genetic modifications of the identity of living forms. Man has the ability to collect individual genes from an organism and insert them into another organism with which the original one would never have been able to mate naturally.[5] Since this is a different technique from that which takes

[5] It should be kept in mind that Article 2 of Directive 2001/18/EC dated 12 March 2001 defines the "organism" as "any biological entity capable of replication or of transferring genetic material", and defines the "genetically modified organism" as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".

There are three promises associated with these novel foods: (1) greater quantities of food, which will make it possible to feed the enormous and increasing world population; (2) healthier food, because the production of GMOs is subject to strict controls; (3) food obtained from less polluting agriculture, because GM plants require a lower level of herbicides and pesticides.

place in nature, considerable debate centres around the question of whether it is morally correct – or not – to engage in genetic engineering.[6] Furthermore, when it is a question of GMO foodstuffs, the concern arises of whether this may give rise to allergies, or even cause more serious harm over the long term, possibly also affecting future generations.[7] Finally, there are worries of threats to biodiversity, which are of relevance inasmuch as the States that signed the 14 June 1992 Rio de Janeiro Declaration (enshrined in Reg. No. 1467/94 dated 24 June 1994) and the Cartagena Protocol (February 1999) and the Montreal Protocol (April 2000) on biosafety undertook a commitment to protect biodiversity. The right to food, i.e. the right to freedom from hunger; the right to be sure that our food is wholesome and health-giving; the right to be informed; the right to demand that the Public Authorities should ensure the highest possible level of protection of the health of humans and of an environment are fundamental aspects of the questions raised by genetic engineering. Consequently, they constitute the "basis" of the rules laid down by the European Union, which centre on the measures specified in article 7.1 of Regulation No. 178/2002, according to which "In specific circumstances where, following an

While these are the definite and certain advantages, the disadvantages are not so certain. But it is known that: (A) between the end of 1998 and the beginning of 1999 a British geneticist, Arpad Pusztai, who reared mice on genetically modified potatoes, noted that the immune system of the experimental mice appeared to be damaged; however, the British Royal Society defined his work as unconvincing; (B) the entomologist John Losey of Cornell University published an article in the 20 May 1999 issue of the American journal *Nature*, detailing his experiments on the Monarch butterfly (a butterfly having orange wings striped with black, which performs an amazing migration every year from the mountains of Mexico to the region that extends from the North-West of the USA up to southern Canada, and then returns to Mexico) reared on Asclepiadaceae dusted with BT maize; Losey noted that butterflies reared on this diet ate less, grew more slowly and had a higher mortality rate; (C) at the end of the 1980s an American company that produces food supplements by using the amino acid known as tryptophan sought to increase its production of the supplements by inserting certain genes into bacteria in order to obtain a greater quantity of enzymes, which it then purified so as to market the food supplements: all this was done without the need to apply for an authorisation from the Food and Drug Administration (FDA) since the method of producing tryptophan (with the use of "normal" bacteria or with the use of genetically modified bacteria) was regarded as irrelevant, due to application of the American principle of substantial equivalence, given that tryptophan had been on the market for years without any reports of toxic effects. But in the case of the genetic modification, the GM food supplements caused the death of 37 people and severe infirmity in over 1500 persons; (D) the September 19th, 2012, number of the journal "Le Nouvel Observateur" published an article by the French biologist Gilles-Eric Séralini presenting the results of his research concerning mice reared on Monsanto's maize NK 603: Séralini found that after 725 days on this diet the mice had developed tumours, whereas Monsanto had declared that after 90 days on the genetically modified maize diet the mice continued to enjoy good health.

[6] The ethical question was taken to the Court of Justice by Holland. The Court noted, however, that the definition of GMO expressly makes mention of "the exception of human beings" (Article 2, Directive 2001/18/EC of 12 March 2001, quoted *supra*, note 4).

[7] The spectre of mad cow disease, which cows had contracted through consumption of animal meal, and the suspicion that cows suffering from this affliction had succeeded in transmitting Creutzfeldt-Jacob disease to man, raises primeval fears among consumers who do not wish to eat foodstuffs deriving from genetically modified agricultural products or who, at the very least, want to know what they are eating.

assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment".[8]

Outline of the Relevant Law

As mentioned above, genetic engineering does not, in principle, conflict with food security: the relevant legislation on this matter is Regulation n. 178/2002 that "provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food" (article 1.1). The production and marketing of genetically modified foods requires application of the procedure of risk assessment by the European Food Safety Authority (EFSA) and risk management by the European Commission, adopted through the precautionary principle. But it should be added that there is a need for technical Community rules to be harmonised with the international technical standards for food and feed and sanitary and phytosanitary standards (Article 13).

Since technical barriers represent the category of non tariff measures that exporters have generally had to face in a worldwide context, the most effective solution would reside in technical harmonisation, to be achieved by participation of the Member States in the *standard-setting* process. This was the main issue in the Tokyo Round that was held from 1973 to 1979 and which led to the formulation what is known as the 1979 *Standards Code*. The main concepts embodied in this Code were the following: it prohibited the use of *ad hoc* technical rules as a basis for

[8] The precautionary principle first arose as a principle designed to safeguard the environment: this approach is found, first of all, in the Declaration on Environment and Development (Conference of Rio de Janeiro, 3–14 June 1992) which states (in principle 15) that: "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"; it is then found in the Cartagena Protocol on Biosafety (Convention on biological diversity, 2002), which states that the "lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question (…), in order to avoid or minimize such potential adverse effects"; furthermore, in article 191.2 of the Treaty on the Functioning of the European Union (TFUE) (previously Article 174 of the Treaty of Rome) in which it is stated that "Union policy on the environment shall (…) shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay". Only later was the precautionary principle extended to food safety, first of all in the Sanitary and Phytosanitary Measures Agreement (attached to the Treaty of Marrakech 1994), according to which Sanitary or Phytosanitary Measures (…) shall be deemed to be necessary to protect human, animal or plant life or health (article 3.2); and subsequently in Article 7 of Regulation n. 178/2002 on food safety.

discriminating against foreign products; it forbade States to introduce unjustifiably restrictive technical rules; it encouraged States to adopt rules based on international standards. The Standards Code acted as the reference point of the Agreement on Technical Barriers to Trade (TBT) of 14 April 1994 approved in Marrakech together with the Treaty on the World Trade Organization (WTO).

The TBT agreement did not, on the other hand, set the standards directly; rather, it made reference to the techniques adopted by other international standardising organisms that establish the techniques by means of their own procedures, although it also took into account the requirements of transparency, information and the procedural terms contained in the *Code of Good Practice for the Preparation, Adoption and Application of Standards* attached to the TBT Agreement.[9] Furthermore the TBT Agreement, unlike the 1979 *Standards Code*, contains a measure that recognises the legitimacy of domestic technical rules insofar as the latter conform to the international reference standards.[10] The WTO report on hormone-treated bovine meat was in line with this presumption of legitimacy and specified that the international standards are technical documents whose observance, on the legal plane, remains voluntary.[11] Moreover, when the WTO Appeal Panel identified the *technical regulations* in the case of asbestos,[12] the Panel stated that the compulsory domestic technical measure should be considered in an overall perspective. So that it would be possible to identify the characteristics a product must obligatorily possess for introduction to the domestic market. The consequence of this statement is, according to the precedents, an extensive interpretation of the concepts of *standard* and *regulation*, which would amplify the scope of application of the rules on technical barriers to trade, giving legal relevance to an enormous mass of regulatory

[9] See article 2.4 of the TBT Agreement: "Where technical regulations are required and relevant international standards exist (…) Members shall use them, or the relevant parts of them, as a basis for their regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems".

[10] See Article 2.4 of the TBT Agreement: "With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardising bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations".

[11] Cf. the WTO Report on hormone-containing meat, with reference to Community Directives 81/602 dated 31 July 1961 and 85/649 dated 31 December 1985, which forbade the use of hormones in feeds destined to bovines, and which justify this prohibition by reference to the danger of tumours that may arise in those who eat meat from bovines whose growth has been enhanced by a diet "rich" in hormones. The European Union's prohibition on the importing of bovine meat obtained from animals fed with hormones led to a clash between the European Union and the United States of America; the dispute was brought to an end, with what was effectively a defeat of the European Union, by the WTO Panel of August 1997, partially corrected by the Appeal Organ of the WTO of 16 January 1998.

[12] Cf. *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products* dated 12 March 2001.

material, sometimes of public origin, at other times of private origin as is the case with the rules of the International Organisation for Standardisation.

Besides, the international Standards, taken in this meaning, are given the limited role of constituting the "basis" of the national technical measures, in the sense that the TBT Agreement allows States not to follow them slavishly if the Standards in question are regarded as ineffective or inappropriate tools for the aims legitimately pursued by the State, either because they cannot concretely achieve the desired results or because they are not suited to reach the desired objective. It should be noted, in this context, that in the case of "sardines"[13] the WTO Appeal Organ decided that the States are required to take international standards into consideration even if their own technical rules came into force before the reference standards were adopted by the international standardisation organisms.

The above mentioned presumption *iuris tantum* of the legitimacy of the national technical rules *in accordance with relevant international standards*[14] does not prevent States from protecting their own public interests that are in conflict with the aim of the free exercise of trade, but only if the international standards are ineffective or inadequate for achieving the aims pursued by the domestic rules. The proper balancing of the opposing interests of trade liberalisation on the one hand, and enhanced product quality and safety on the other, has as its reference criterion the principle of reasonableness, as expressed in Art. 2.2. of the TBT Agreement.[15] According to WTO precedents and the interpretation of the legal case histories, the balancing is performed on the basis of three specific tests, known, respectively, as: the *suitability test*, which requires case by case verification of the legitimacy of the aim pursued; the *necessity test*, which assesses whether the point has been reached beyond which the technical rule is an "unnecessary" obstacle to international trade; and the *proportionality test*, designed to assess the negative effects of the domestic rule on trade.

It should also be pointed out that the recent Proposal for the Regulation establishing a common organisation of the markets in agricultural products provided that "A product shall be considered as conforming to the general marketing standard where the product intended to be marketed is in conformity with an applicable standard adopted by any of the international organisations listed in Annex V". The

[13] Cf. *European Communities – Trade Description of Sardines dated* 26 September 2002, which, in point 208 of the decision, states: "Furthermore, like Articles 5.1 and 5.5 of the SPS Agreement, Article 2.4 is a 'central provision' of the TBT Agreement, and it cannot just be assumed that such a central provision does not apply to existing measures".

[14] Article 2.5 of the TBT Agreement continues: "…it shall be rebuttably presumed not to create an unnecessary obstacle to international trade".

[15] Article 2.2 of the TBT Agreement asserts that the national technical rules cannot be "more trade-restrictive than necessary to fulfil a legitimate objective"; it thus indicates the national security requirements, the prevention of deceptive practices; *protection of human health or safety, animal or plant life or health*, or environment as "legitimate objectives"; finally it identifies as "relevant elements of consideration" the available scientific and technical information, *the related processing technology* or the intended end-uses of products.

measure was strongly criticised, so that it is not present in the definitive version of the Regulation on the Single CMO Organisation.

Another aspect to be borne in mind is the OECD principle of the substantial equivalence between traditional and genetically modified products, on the basis of which a type of label emphasising the genetically modified nature of the foodstuff would not be admissible.

Admission

Restriction of GMO

It is necessary, firstly, to point out that the European Union (and not the individual Member States) is entrusted with authorising the cultivation of genetically modified seed and the marketing of genetically modified foodstuffs (see *infra*, section "Admission of GMOs in food production").

In Europe, there had been a sort of moratorium since 1998, as from that date onwards the Community authorities had given no answer to the authorisation requests submitted by foreign multinationals that wished to market their genetically modified seed in Europe. In 2003, the United States, Argentina and Canada challenged the European Union's attitude, and on 29 September 2006 the WTO Panel judged the European Union to be in the wrong, asserting that Directive 90/220 (as replaced by Directive 2001/18) and Regulation No. 258/97 on genetically modified organisms were in contrast with the Agreement on Sanitary and Phytosanitary Measures (SPS) attached to the 1994 Treaty of Marrakech. The claimants argued that the Community regime of approving biotechnological products is a Sanitary and Phytosanitary Measure (SPS), and therefore the moratorium had incontrovertibly led to an unjustified delay in bringing to an end the procedure which the European Union had set itself the task of completing, in order to grant or deny the requested authorisations. Note that the SPS Agreement does allow WTO Member Countries to introduce more protective measures for the safeguarding of humans, animals and plants (Art. 3.3), and at the same time the Agreement submits the requests advanced by importers to a procedure of *decision without delay*, in order to determine whether the requests are in conformity with such measures (Art. 8). The European Union, for its part, argued that the complexity of the problem of biotechnologies, and indeed the very uncertainty within the scientific community itself, as well as the inadequate knowledge of the effect of biotechnologies both on human health and on the environment, had led to a situation, even within the Union itself, of intertwined proposals and changes in the rules which, taken together, and after prolonged debate, had resulted in the new Directive 2001/18 and the new Regulations Nos. 1829 and 1830/2003. This, obviously, had influenced the specific and distinct procedures involving authorisation requests, and had called for prolonged examination by the Community organisms, which were required to pursue not only the goal of protecting the health of humans and animals according to the SPS Agreement,

but also that of protecting the environment and the ecosystems, in accordance with the other international treaties, including the Agreement on technical obstacles to trade or TBT. Consequently, it was maintained by the European Union that inasmuch as the measures adopted were aimed (also) at protecting the environment and conserving biodiversity, they should be considered as reasonable and legitimate, but also as not necessarily having a Sanitary or Phytosanitary character: on the contrary, they were totally or at least in part outside of the field of application of the SPS Agreement. In other words, the European Union asserted that its prudent behaviour was in conformity with the approach which the other international treaties, such as the Cartagena Protocol, had established when they introduced the precautionary principle; this, in the view of the European Union, implied that the passage of time (i.e. the failure to give a *decision without delay*) could have been defined as unjustified only if all the authorisation requests had not been examined individually on a case by case basis: and it was up to the Panel to determine whether, in any individual procedure, there had been a real delay or whether the European Union's behaviour in causing an alleged delay actually had a legitimate justification.

For the Panel, protection of the environment – which appears among the considerations of Directives 90/220 and 2001/18 – has as its final and fundamental goal that of protecting the health of humans animals and plants, i.e. the goal which is also pursued specifically by the SPS Agreement. The consequence is that to the extent to which Directives 90/220 and 2001/18 are applied in order to protect animals and plants in the framework of protection of the environment, the Directives in question are not excluded *a priori* from the field of application of the SPS Agreement. On the contrary, they are SPS measures capable of directly or indirectly affecting international trade; accordingly they are subject to the terms prescribed by the SPS Agreement, which – as mentioned above – lays down that procedures should be performed without unjustified delay.

As far as Italy is concerned, the problem has been raised of whether the Regions could declare their territory, as a whole or in part, to be *GMO-free*. Prior to the Recommendation of the European Commission dated 23 July 2003 (now replaced by the Recommendation dated 13 July 2010), and therefore prior to Decreto Legge 279/2004, and also prior to European Community Directive 2001/18 on deliberate emission of GMOs into the environment, a number of Italian Regions (for example the Region of Latium with Law No. 53 dated 1 March 2000; the Region of Tuscany with Law No. 53 dated 6 April 2000; the Region of Abruzzo with Law No. 6 dated 16 March 2001; the Region of Umbria with Law No. 21 dated 20 August 2001) had banned the cultivation, in certain areas of their respective territories, of genetically modified plants; subsequently, after Directive 2001/18, the Regions of Marche and Puglia (with Laws No. 5 dated 3 March 2004 and No. 26 dated 4 December 2003, respectively) banned GM crops throughout their territories.

Therefore, there exist some Italian Regions that have declared their own territory to be GMO-free. It should also be borne in mind that the safeguarding clause of directive 2001/18 on deliberate emission of GMOs into the environment (Art. 23) admits the possibility for States to ban GM crops in their own territory for reasons pertaining to the safeguarding of health; note that this clause is a specification of the

general safeguarding clause embodied in Art. 114 of TFUE. Furthermore, Art. 26-*bis* introduced (by Reg. 1829/2003) into the body of Directive 2001/18 lays down that "the Member States can adopt all the appropriate measures in order to avoid the involuntary presence of GMOs in other products", and this does not jeopardise the possibility for Member States to resort to the emergency measures cited in Art. 34 of Reg. 1829/2003.[16]

Now, it is important to note that Sentence No. 183 dated 19 January 2010 issued by the Consiglio di Stato (i.e. the Italian Council of State), which recognised that the Decreto Legge 279/2004 was the outcome of the *exclusive legislative competence* of the State in matters pertaining to environmental protection, and the outcome of *concurrent* competence in questions pertaining to health, concluded with a ruling that required the "repeal, due to incompatibility, of the prohibitions and limitations introduced in some regional laws, pertaining to genetically modified crops." Therefore, according to the highest Italian administrative judge, the laws banning GMO products passed by the Regions that had declared their territories to be GMO-free should not be applied.[17]

In conclusion, it is helpful to mention that a proposal for a regulation of the Parliament and the Council (COM(2010) 375 def. of 13 July 2010) is *in itinere*; it intends to insert into Directive 2001/18 the Art. 26-*ter*, by which "the Member States can adopt measures that limit or forbid the cultivation of all or of certain specified GMOs throughout their territory or in part of it", even if these GMOs have already been authorised pursuant to Reg. 1829/2003, provided that the measures in question are based on "reasons other than those associated with assessment of the negative effects on health and the environment" (given that such reasons have already been considered at the moment of Community authorisation) "and provided

[16] In this regard it is useful to recall the case of the Land of Upper Austria, which intended to ban genetically modified crops throughout its territory, by appealing to Art. 95.5 (which was in force at that time) of the Treaty of Rome, which stated that when there is a harmonised Community rule (as was the case for the Directive on the deliberate emission of GMOs into the environment), a Member State which believes it is necessary, on the basis of new scientific evidence, to introduce measures for the *protection of the environment* (or of the workplace) must notify the Commission in this regard. More specifically, the Land of Upper Austria had submitted to the Commission a draft bill of a ruling that would forbid the utilisation of biotechnology in agriculture; in submitting its draft, the Land of Upper Austria invoked the provisions laid out in Art. 95.5 of the Treaty of Rome (now Art. 114 of the TFUE). First the Commission, then the Court of First Instance (Sentence dated 5 October 2005, T-366/03, *Austria v. Commission*) and then the Court of Justice (Sentence 13 September 2007, C-439/05 and C-454/05, *Austria v. Commission*) rejected the request for authorisation, because it had not been demonstrated that the territory of the Land of Upper Austria contained special or exceptional ecosystems such as would have required a purpose-instituted risk assessment and such as would thus have warranted the prohibition on GM crops, given, also, that the justifications adduced pertaining to the limited surface area of farms in the Land in question and to their special vocation of organic farming had been rejected as insufficient.

[17] The same conclusion is probably reached if, on the assumption that the regional formulas are technical rules, it is pointed out that the various laws of those Italian Regions that have declared their territories to be GMO-free were not notified to the Commission, as should obligatorily have been done – under pain of absence of force of the technical rule – pursuant to Directive 98/34 dated 22 June 1998.

that they are in conformity with the treaties" (that is to say, with Arts. 34 and 36 of TFUE on the free circulation of goods and with the principle of non discrimination between national and non-national goods). Additionally, the Member States must also compulsorily submit a specific note of information to the Commission, because the procedure laid down in Directive 93/84 concerning the notification and information on national technical rules is no longer regarded as an appropriate channel. The report annexed to the above-described proposal also states very clearly that the new Art. 26-*ter* "is exclusively concerned with the freedom of Member States to forbid/limit the *cultivation* of the GM varieties" on their own territories "on the national/regional/local level", underscoring not only that the modification "does not concern the free marketing of GM seed authorised on the EU level or the importing of EU-authorised GM seed from third countries", but also that the impact assessments to justify the prohibition or limitation of GM cultivation can be adopted, in the States whose constitutional organization provides for such measures, by the regional or local territorial Bodies.

Admission of GMOs in Food Production

The European Union does not allow anyone to introduce GMOs into the Union without having first obtained an authorisation through a complex procedure. Directive 2001/18 (like the preceding 90/220) contemplates two distinct situations: intentional introduction into the environment (for instance, by sowing in the field), or introduction of products into the market. Both aspects require an assessment of the ecological impact of GMOs in the natural environment and also of the risk for human health due to the use of GMOs. In particular, the potential impact of GMOs on the environment requires consideration of the likelihood that the GMO may become persistent and invasive in natural habitats, leading to the risk of transfer of the modified gene to other species and interaction of the genetically modified organism with other organisms. The possible immediate and/or delayed effects on human health mean that it is crucial to consider the potential interactions between GMOs and men and animals.

With regard to the authorisation procedure, the current starting point is Regulation n. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.[18] Such novel foods and ingredients

[18] In addition to (a) foods and food ingredients containing or consisting of genetically modified organisms; (b) foods and food ingredients produced from, but not containing, genetically modified organisms, the following are also *novel foods*: (c) foods and food ingredients with a new or intentionally modified primary molecular structure; (d) foods and food ingredients consisting of or isolated from microorganisms, fungi or algae; (e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use; (f) foods and food ingredients which have undergone a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food

included foodstuffs containing or constituted by GMOs, as well as foodstuffs produced by starting from GMOs, even if the foodstuffs in question no longer actually contained the GMOs.[19] The Regulation required that prior to the introduction of such products onto the market, they should be submitted to a complex "standard" assessment procedure, which should be a single procedure but decentralised, and which was reserved to new products or new food ingredients that contained or were constituted by GMOs. On the other hand, no procedure was required, at that time, for foods that had been obtained by starting from GMOs but which now no longer contained them. The procedure became "simplified" because it consisted of a mere requirement of a direct notification to the Commission, if the *novel foods* were "substantially equivalent to existing products or ingredients" as far as their nutritional value, metabolism, intended utilisation and absence of undesirable substances was concerned.[20]

The subsequent Regulations No. 1829/2003 and No. 1830/2003 of 22 September 2003 profoundly influenced the subject of the foodstuffs defined as "new" when they were genetically modified.[21] These Regulations confirmed the rule whereby

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ingredients which affect their nutritional value, metabolism or level of undesirable substances (Article 1.2). The novel foods must not present a danger for the consumer, mislead the consumer, differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer (article 3.1).

[19] In 2008 the Commission formulated a proposal for modification of Regulation 258/1997 on novel foods; the proposal, among other things, clarified the definition of "novel food" taking into account the new technologies that have an impact on foodstuffs. The proposal was not adopted because the Council and the European Parliament failed to reach an agreement during the dispute settlement procedure, after the Parliament had proposed various amendments both during the first reading (25 March 2009) and the second reading (7 July 2010).

[20] The *discrimen* between the standard and the simplified procedure – the latter being characterised by mere notification to the Commission – was given by the equivalence of the novel food to the product already existing in nature. The recognised equivalence between novel food and the corresponding conventional food was held to be sufficient evidence that the novel food, precisely because it was equivalent to the conventional food, would be "safe" just as the conventional foodstuff was safe. Once the equivalence had been ascertained, the obligation to indicate on the label that the new food consisted of or contained GMOs was no longer imposed. The labelling obligation was also lifted when the novel food, although produced by starting from GMOs, non no longer contained any GMOs.

[21] The European Union intends to take action with regard to Regulation No. 258/97, including the "residual" parts that remain after the interventions of Regulations 1829 and 1830 of 2003. In particular, the Community aims, through the proposed modification put forward on 14 January 2008 [COM (2007) 0872 def.], to replace the earlier distinct procedures – maintained for the other novel foods – by a single centralised assessment procedure, and at the same time to give a single definition of "novel food" as one that "is not found to have been used to a significant extent for human consumption within the Community prior to 15 May 1997". Such a definition seeks to gather together in a single definition all four of the previous definitions, which were governed by Regulation No. 258/97 on novel foods after the "transfer" of the rules on genetically modified foods into Regulation No. 1829/2003. This unified definition would make it possible to include any foodstuffs that new technological processes, such as cloning, nanotechnology and nanoscience, could potentially create. Thus the proposal for modification of Regulation 258/1997 on novel foods aims to clarify the definition of "novel food" taking into account the new technologies that have an

any product containing or derived from GMOs is a novel food; additionally, the Regulations laid down that the new rules should also apply to products that had made use of genetically modified organisms even if, after the production process, it were no longer possible to find residues of genetically mutated DNA or proteins in such products. Finally, the decentralised procedure was deemed to be no longer applicable, because today the use of GMOs for producing foodstuffs requires a special authorisation according to a specific procedure that is centralised at the Commission.

In other words, Regulation No. 258/97 has been replaced by Regulation 1829/2003 as far as genetically modified foodstuffs and feed are concerned, while it remains in force for all novel foods of a *different nature*. More precisely, "no-one can introduce onto the market a GMO destined to human consumption (…) unless an authorisation (…) has been granted for the product and unless the corresponding conditions of the authorisation are respected" (Article 4.2). The authorisation procedure requires the opinion of EFSA, and the Commission will then use this opinion as the basis on which to present a decision-making process which is submitted to the Permanent Committee for the Food Chain. The Committee then makes its decision, taking into account the provisions "any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the graft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences" (Article 7.1).[22]

Threshold Values

Community law (and therefore, Italian law) admits a tolerance threshold of accidental contamination by GMOs, but the level of GMOs must not exceed 0.9 %. More specifically, Article 12.2. of Regulation n. 1829/2003 establishes that the Section on labelling "shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 per cent of the food ingredients considered individually or of the food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable" The consequence is that the absence of an indication stating, on the label, that the product contains GMOs is not unlawful if the GMO food product respects the rules in force that concern the labelling of such products and which make it possible for the mention of the presence of transgenic derivates to be omitted on the label, provided that they are present to an extent not exceeding 0.9 %. If their presence is greater than

impact on foodstuffs. As mentioned earlier in note 19, the proposal was not adopted because the Council and the European Parliament failed to reach an agreement during the dispute settlement procedure, after the Parliament had proposed various amendments both during the first reading (25 March 2009) and the second reading (7 July 2010).

[22] On the rules governing this scientific Committee see, Regulation No. 182/2011 dated 6 February 2011.

0.9 %, and if that specific genetically modified foodstuff has obtained the authorisation for introduction on the market, then it is compulsory for the presence of GMOs to be stated on the label.

Implementation and Enforcement, Controlling Regime

Community law is based on the principle of mutual recognition, in the sense that a legal measure enacted in a Member State with regard to a given good is valid for the circulation of that good in all the other Member States. Naturally, this principle holds even more clearly if the measure has been enacted by the European Union Authorities. It follows that a Member State is not allowed to ban a seed variety from its national register of plant varieties merely because of its genetically modified nature, if the GM seed was authorised by the Member State while Council Directive No. 90/220 was in force, or by the Commission while Directive 2001/18 was in force. This line of reasoning was the basis for the judgement pronounced by the Court of Justice in the sentence dated 16 July 2009, in the case C-165/2008, *Commission v. Poland*. By the same token it is not possible for one Member State to invoke the special scenic value and the natural beauty of its landscape in order to ban the sowing on its own territory of seed authorised by the European Union: sentences confirming the unlawfulness of such a ban have been handed down both by the Court of First Instance, 5th October 2005, in the cases T- 366/03 and 235/04, and also the Court of Justice 13 September 2007, in the joint cases C-439/05 and 454/05, *Austrian Land Oberösterreich v. Commission.*

Labelling Regime

Labelling

The most severe problem raised by biotechnology in agriculture is the uncertainty concerning the effect of transgenic crops on human health and on the environment. Protection of health is emphasised above all with regard to communication in the context of the agrifood market, i.e. with regard to the "sign" associated with the genetically modified product when it enters into the market. The most relevant aspect for the purposes of delineating the main lines of agrifood law within the European Union is the aspect concerning the "sign", which makes it possible to acquire information concerning GMO foodstuffs. It is therefore necessary to analyse the last segment of what is known as the biotechnology food chain, which can be decomposed into the following phases: the phase of utilisation purely for research and for study of the biotechnological material; the potential phase of patenting the procedure and the biotechnological product; the subsequent phase in which debate has decided in favour of deliberate emission of the genetically modified organism

into the environment for the purpose of growing crops; and finally the phase of introducing onto the market the genetically modified foodstuffs that it has been possible to grow and produce. All these stages require specific authorisations.

In order to understand the problem of the labelling of the product as constituted by or derived from a GMO, or – alternatively – as GMO-free, it is helpful to outline the "procedure" through which a genetically modified plant is obtained. The gene of an organism of a certain species is "cut" from the donor organism and inserted into the genetic endowment of a different organism – the recipient – which could even belong to a different species. And to gain insight into the ongoing diatribe between the USA and the European Union, it should be recalled that unlike the procedures of crossing and selection, by means of which *new individuals* are created, as demonstrated by the fact that the law requires them to be given a name to distinguish them from others [for plants, this is done by what is known as the varietal denomination], in the case of genetic manipulation procedures the result is quite different: what is obtained is *the same individual as before*, but its genetic endowment has been modified by means of the insertion of another individual's gene into its genoma. Starting from the fact that the genetically modified individual is the same individual as before, even though its genoma has been modified by man, the United States examines whether the genetically modified product is identical to the traditional foodstuff in terms of levels of proteins, vitamins, nutritional value, carbohydrates, minerals and fats. If the product satisfies the requirement of *substantial equivalence*, then this implies application of the principle of transitivity: in other words, if the traditional food is safe, then the GM foodstuff is also safe. The USA has embraced the principle of substantial equivalence, because the "focus of interest" for US policy resides in the "result" of the operation of genetic manipulation, i.e. in the product; in contrast, the European Union argues, in opposition to this view, that the "procedure" is different from the natural course of events, and therefore the traditional product and the GM product could never be defined as equivalent. It follows that there is a need to transmit this information to the consumers.

As mentioned earlier, it is important to emphasise that Regulation No. 1829/2003 lays down the rules concerning the labelling system,[23] establishing that in *all* cases

[23] By means of Regulation No. 258/97 dated 27 January 1997, the European Union declared that the new products and new food ingredients must bear a label indicating the presence of GMOs. Regulations Nos. 1829/2003 and 1830/2003, both dated 18 October 2003, reiterated this obligation. Therefore, probably due to concerns about the risk of so-called "mad cow disease", and also responding to demands stemming from consumer organisations and the media, the European Union has introduced a series of provisions, all of which are designed to ensure full achievement of the right to adequate information, according to two distinct channels: one concerns the labelling of all food products (Directives 79/112 and 2000/13), while the other deals with the labelling of specific GM foods (Regulations Nos. 258/97, 49 and 50/2000; Directive 2000/18; Regulation No. 1829/2003).

The contrast between Community Law and the legal system in force in the United States, Canada and Argentina is very clear-cut. On account of the principle, maintained by these three countries, of substantial equivalence between traditional agricultural products and genetically modified agricultural products, labels indicating the presence of GMOs in the products cannot be admitted.

of foodstuffs obtained with genetically modified products it is compulsory to indicate that they contain or are derived from GMOs. However, this obligation does not exist if the foodstuffs contain or are constituted by or are produced by starting from GMOs present in a proportion not exceeding 0.9 %, provided that such presence is accidental or technically inevitable.

Furthermore, Regulation No. 1830/2003 lays down the rules for the traceability of GMOs, by means of a single identifier, a simple numerical or alphanumerical code to be used in order to maintain control over all the information on the product transformation processes. This should make it possible to keep GM production under control, ensuring that the GMOs are detectable and "traceable" even in the absence of verifiable residues of genetically modified proteins.

In short, given that Community rules are based on the manner of risk assessment and risk management detailed in Regulation No. 178/2002 on food safety, they make it possible to build up a clear-cut body of rules that shapes the essential fabric of the specific market of genetically modified foods, effectively establishing it as *one* of the various food markets of the European Union. The foodstuffs belonging to this market "bear" a distinctive sign, namely, the sign of genetically modified foodstuffs.

Legislation Addressing Labelling Fraud

Competition, in the legal sense of the term, is not merely a series of rulings to govern the relations among competitors. It also involves rules concerning selection on the part of consumers, who select from among various different entrepreneurs, and rules governing the relations between consumers and the extensive range of enterprises. The first of these three aspects of competition finds expression in the prohibition against certain forms of conflict and in action against restrictive agreements or against avoidance mechanisms designed to subvert competition among entrepreneurs, while the third aspect implies a system of constant exposure of entrepreneurs to the competitive struggle and the risk of losing. On the other hand, the second of these three aspects consists in guaranteeing the quantity and quality of information that will enable the consumer to make a conscious choice. In this report attention focuses on the effects of the guarantee of information.

Now, while entrepreneurs on the market are exposed to the constant risk of failure, consumers are likewise exposed to a risk, namely that how to make their own individual choice, given that consumers cannot transfer to others the unknown factors of their decisions. And the risk associated with choice is by no means insignificant when it is a question of food: the choice may affect one's health or even one's very life itself and that of one's children. Therefore the risk involved in the decision to choose a GMO food product implies that consumers must be in a position to know what they are eating.

But just as the producer's entrepreneurial risk has a corresponding element in the risk which, as described, forms part of the consumer's choice, it is advantageous for

the entrepreneur, in a mirror image view of the situation, to communicate to consumers what they "need to know" for their choice. This is leading to the compartmentalisation of a "new" market, a market in which the products are signalled as "produced with GMOs".

Failure to indicate the presence of GMOs on the product label gives rise to liability and could probably become the basis for suing on the basis of unfair competition, because in a compartmentalised market like that of genetically modified foods, a producer who abides by the rules would suffer damage due to the false omission of the presence of GMOs on the labels of rival products.

Liability

Genetic Technology

The damage deriving from placing GMO products on the market can affect the health both of the entire collective community and also of the individual consumer of a GMO-based product.

With regard to the potential damage inflicted on *collective health* by GMO products, it should be stated straight out that health is considered in Art. 191 TFUE (which includes the protection of health among the objectives of environmental policy) and in Art. 168 TFUE (which establishes that the requirements of the protection of health are a component of other Community policies). Additionally, within the Italian legal system it is a constitutionally guaranteed and super-ordered right (Art. 32 Const.).

From the perspective of Community law, it is important to note that EU powers in matters of health are not exclusive. Thus it is conceivable that the Member States may pass more restrictive rules for the protection of health, and such restrictions would not constitute illegitimate limitations on the importing of products affected by the prohibition, given that Art. 36 TFUE admits such restrictions precisely for the purpose of protecting citizens' health. Therefore, by virtue of the principle of subsidiarity that is valid for matters of shared competence, as is the case of the protection of health, it may be considered possible that an individual State could intervene, with measures that are appropriate, necessary, reasonable – indeed they must respect the principle of proportionality and the precautionary principle – and limit or forbid the marketing of genetically modified products on its own territory in order to achieve a higher level of protection of the health of its own citizens. Breach of the rules implies a liability, which should properly be addressed by the individual Member State in the framework of public law, with criminal or administrative penalties.

More generally, it is also necessary to keep in mind that the European Union has no authority in matters pertaining to criminal punishments or pecuniary penalties: Article 33 of Directive No. 2001/18 merely states that "Member States shall determine the punishments or penalties applicable to breaches of the national provisions

adopted pursuant to this Directive. The punishments or penalties shall be effective, proportionate and dissuasive". And indeed Italy, with Decreto legge No. 224/2003, inflicted criminal punishments on the breaches regarded as most serious, and a pecuniary penalty for minor violations. This means that in order to protect human health and the environment, Italy takes action with regard to the deliberate release of GMOs into the environment in cases where this emission occurs without prior notification to the National Authority[24] or without waiting for the authorisation to be issued following the notification, or despite the authorisation having been refused or repealed,[25] or without obeying the requirement prescribed in the authorisation provision.[26]

As far as concerns breach of the obligations pertaining to the placing of GMO products on the market, three types of breach are defined: failure to undertake the notification, absence of authorisation, and failure to comply with the measures laid down in the authorisation provision. These three types of breach give rise, respectively, to criminal penalties in the first two cases, and administrative sanctions in the third case. But there is also a fourth hypothesis of liability of a producer who, after having notified the competent national authority and after obtaining the authorisation for release of a GMO onto the market, becomes aware of new information on GMO-related risks for human and animal health and for the environment but does not immediately adopt all the necessary safeguarding and protection measures, or does not communicate the aforesaid information to the competent national authority.[27]

On the question of the potential damage inflicted on *individual health* by the marketing of GMO products, it cannot be excluded that individual consumers of GMO foodstuffs may suffer damage as a result of ingestion of such foodstuffs. In this context, it is relevant to cite Article 21 of Regulation No. 178/2002 on food law, which refers back to Council Directive No. 85/374/EEC of 25 July 1985 concerning liability for defective products, mentioned in this report sub point 4.1. This is a question pertaining to civil liability, which is specific to European Union Law and to the law of each Member State: it is a *strict liability* which concerns Civil Law. It should nevertheless be borne in mind that the above-mentioned Directive's provision allows Member States to exclude responsibility in the case of what is known as

[24] This is a breach that is punished as a criminal offence, by arrest for a period ranging from 6 months to 3 years, or with a fine up to euro 51,700 (fifty-one thousand seven hundred) (Article 35.1, Decreto legislativo 224/2003).

[25] This is a breach that is punished as a criminal offence, by arrest for a period ranging from 6 months to 2 years, or with a fine up to euro 51,700 (fifty-one thousand seven hundred) (Article 34.2, Decreto legislativo 224/2003).

[26] This is a breach that results in a fine ranging from euro 7,800 (seven thousand eight hundred) to euro 46,500 (forty-six thousand five hundred) (Article 35.5, Decreto legislativo 224/2003).

[27] This is a breach that is punished as a criminal offense, by arrest for up to 2 years, or with a fine up to euro 51,700 (fifty-one thousand seven hundred), in the first case (Article 35.6, Decreto legislativo 224/2003), while in the second case there is a fine ranging from euro 7,800 (seven thousand eight hundred) to euro 46,500 (forty-six thousand five hundred) (Article 35.8, Decreto legislativo 224/2003).

development risk, i.e. when the harmfulness of a product is discovered only after its release onto the market. In other words, the producer is responsible only for the damage that is predictable on the basis of the best knowledge available at the time of production. Italy has adopted this exemption clause: accordingly, if at some future time the damage that has affected a consumer proves to be attributable to consumption of a GMO food, the producer would be exonerated from all responsibility.

Moreover, there is also another case in which exemption holds, involving the consequences of the labelling of GMO products, as mentioned earlier. The producer is exonerated from strict liability when citizens are aware of the risks they are taking when they "use" a given product. Now, if the label indicates the presence of GMOs, it makes citizens aware of the risk of damage that could be inflicted on them by consumption of the food product in question. Consumers who voluntarily consume the GMO product even though they are aware of the risk relieve the producer of liability for the damage they have suffered. In other words, the Community authorisation allowing GMO products to be placed on the market and the compulsory presence of the label ends up "offloading" onto the consumer any damage arising from consumption of GMO foodstuffs.

However, it should also be noted that Article 7.7 of Regulation No. 1829/2003 on the centralised procedure of GMO authorisation, establishes that "the granting of authorisation [by the Community Authorities] shall not lessen the general civil and criminal liability of any food operator in respect of the food concerned".

The *damage* resulting from a genetically modified crop may also affect *neighbouring crops*. The European Union has addressed the problem of the coexistence among transgenic, conventional and organic crops, in the awareness that once genetically modified crops have been authorised, traditional or organic crops could be accidentally "contaminated" by genetically modified crops, as a result of pollination or inadvertent mixture of products during harvesting, or during transport or storage, or through the production of new self-set plants from GM seed left in the ground after harvesting. It is not the task of the European Union to deal with civil liability for damage; therefore the Union has not introduced specific provisions on this matter. However, starting out from the principle that the freedom of enterprise implies farmers' freedom to choose among the different modes of production, the Commission issued a Recommendation dated 23 July 2003 (now replaced by the Recommendation dated 13 July 2010) and, invoking the principle of subsidiarity, and invited the Member States to draw up and implement national strategies aimed at identifying management measures that would be feasible (from the cost point of view as well) and which would minimise the risk of mixture and contamination deriving from the coexistence of different crops. Italy took action to implement the suggestion, with the Decreto legge No. 279 dated 22 November 2004, converted into law, with modifications by Law No. 5 dated 28 January 2005. However, many of the provisions of the afore-stated Decreto legge were declared illegitimate by the Italian Constitutional Court, with Sentence No. 116 dated 17 March 2006, on account of invasion by the State into matters belonging to the sphere of competence of the Regions. This notwithstanding, the Court confirmed that the State was acting

within its powers with regard to the guarantee of freedom of enterprise, in the sense that farmers cannot be prevented from choosing whether to grow genetically modified crops or traditional crops or organic crops, provided that they take note that they would be held responsible if their own transgenic crops were to cause damage to neighbouring crops. By the same token, the Court confirmed that the State was the competent organ with regard to rules involving compensation for any damage caused by transgenic crops.

The problem of the economic damage potentially inflicted on conventional or organic farmers if their crops come into contact with pollen from neighbouring genetically modified crops had already been raised earlier by Italian law scholars, and a possible solution had been found in Art. 844 of the Civil Code concerning a prohibition on the emission (now reformulated by Law No. 13 dated 27 February 2009 at the moment of conversion of Decreto legge No. 208 dated 30 December 2008, albeit with regard to acoustic emissions). Decreto legge 279/2004, which required all farmers who cultivated transgenic crops to draw up, in the framework of the regional coexistence plan, their own business management plan starting from the very moment when they intend to grow a genetically modified crop, established in Art. 5 that whoever suffers damage has the right to be compensated by the transgenic farmer who has failed to comply with the regional coexistence plan and with his/her own business management plan. This is a form of liability in tort, and fault-based, which, however, involves inversion of the burden of proof: thus it is the person that causes the damage who has to prove that he/she has observed the measures laid out in the afore-stated regional plans and his/her business management plan, in order to be relieved of from any liability. It should further be specified that the farmer's liability is totally excluded if the farmer whose transgenic crop has caused the damage actually utilised seeds certified by the public authorities, and supplied with a declaration by the seed company concerning the absence of GMOs. In this case the liability for damage caused is borne by the suppliers of the technical means of production and by the other operators of the primary production chain.

A further point that should be mentioned is that the Italian Law Decree 279/2004 allows the possibility of identifying specific insurance tools designed to support the burden weighing on those responsible for breaching the coexistence rules (Art. 5.1 *ter*), assigning to the Regions the task of setting up a fund for restoration of the agronomic conditions existing prior to any harmful events that could result from failure to comply with the coexistence plan (Art. 4.3*bis*).

The Italian legal provisions are completed by heavy sanctions, which can involve criminal or administrative law. The establishment of transgenic crops before the regional coexistence plans have been adopted is a criminal offense (Art. 6), unless the transgenic crops in question have been authorised for purposes of research and experiments (Art. 8). In contrast, penalties occur in cases of failure to comply with the technical rules of the regional coexistence plan, or if the farmer uses genetically modified seed that has not been authorised by the European Union or by the Region that is involved as the competent authority. In effect, in the Italian legal system, a farmer who wishes to grow transgenic crops must request and obtain the authorisation of the Region where the crop is to be grown.

Product Liability

Council Directive 85/374/EEC of 25 July 1985 (as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999) on the approximation of the laws, regulations and administrative provisions of the Member States concerns the liability for defective products.

The traditional rule on compensation for damages deriving from defective products was that the person who had suffered the damage brought a case for liability against the seller and/or engaged in an *actio legis Aquiliae* (i.e. suing for liability in tort) against the producer. Due to the ease with which sellers succeed in demonstrating that they "were guiltlessly unaware of the defects of the thing" and on account of the difficulty encountered by the buyer in demonstrating the liability of the producer in a case of suing for liability in tort, the degree of protection of the claimant against product defects generally becomes inadequate. For this reason, in the 1960s, United States law scholars built up a body of rules that was coherent with the precedents forming part of the economic analysis of law. When they compared the economic effects of the traditional rule of non-existence of liability without fault to the effects obtainable by a new rule of strict liability, they concluded in favour of the objective imposition, on the production companies, of the risks deriving from the companies' activity. The United States body of precedents suggests that the producers would thereby be in a better position to prevent or reduce these risks, and the additional costs deriving from shouldering the risks, in the form of insurance contracts, correlated with very minor price rises, could be passed on to the purchasing consumers.[28] In 1985 the European Community endorsed these considerations and issued Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

The fundamental rules are that: "the producer shall be liable for damages caused by a defect in his product" (Article 1); "a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account" (Article 6); "the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage" (Article 4). However, the producer will be relieved of liability if he can prove, among other things, "that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered" (Article 7, letter *e*, on what is known as the "development risk"), unless otherwise stated in measures passed by the Member States (Article 15). By the same token, "the liability of the producer may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person" (Article 8.2).

[28] Section 402 A of Restatement (Second) of Torts of 1965 introduces the rule of strict liability in tort into the United States legal system; that is to say, it introduces the rule of the objective liability of producers for any harm caused by their defective products.

The last two provisions stated above may be relevant in the context of the use of GMOs. In effect, with regard to the penultimate provision, it may well be the case that the state of scientific and technical knowledge had contributed to the claim that the genetically modified food presented no risk at the time when the product was put into circulation, whereas subsequently, new scientific knowledge demonstrated the harmful nature of the genetically modified food. If the Member State – as is the case for Italy (Article 6 of Decree No. 224 of the President of the Republic dated 24 May 1988, now Article 118 of the Consumer Code dated 9 November 2005 No. 206) – adopted the rule of exoneration from liability if the risk were to come to light as a result of scientific progress, then the producer of genetically modified foods will not be liable for damages caused by his product.

The last provision could have greater significance in the context of the use of GMOs. In European Union law, genetically modified products are required to be labelled with the words "contains genetically modified" and the liability can been disallowed in case of fault by the injured person; in Italian law "compensation is not due when the person who has suffered the damage was conscious of the product defect and of the danger deriving from such defect, but nevertheless voluntarily exposed himself/herself to the danger" (Article 122, of the Consumer Code). Therefore, the producer should be exonerated from any liability if it is demonstrated that the consumer made use of the good while having knowledge of its defect – in the case of genetically modified foods, knowledge of danger to his/her life or health. In other words, it can be stated that when consumers make use of food which is clearly indicated as having undergone genetic modification, they have spontaneously exposed themselves to the "danger" deriving from the genetically modified organism. In short, the label has the effect of making the consumer bear the burden of risk management; thus it can be stated that in Italian law there is a shifting of responsibility from the producer to the consumer.

Additional Information

Brief Summary of the Issues and Relevant Paragraphs

Italy is part of the European Union and is therefore required to comply with EU rules on matters concerning GMOs (see above, sections "Use of GMO in food production" and "Food security").

The citizens and institutions of the European Union have expressed concern with regard to the effects of GMOs on the environment and human health (see above, sections "Use of GMO in food production" and "Legal superstructure").

Similar concerns have been voiced by Italian citizens and by the Italian Government (see above, section "Use of GMO in food production") and also by some Italian Regions which have declared their respective territory to be GMO-free (see above, section "Restriction of GMO").

With regard to the issue of a more restrictive national regulatory system on GMOs than the EU rules, in order for this to be admissible it should be kept in mind that within the European Union, the protection of health is a matter of shared competence between the European Union and the Member States; therefore the principle of subsidiarity holds (see above, section "Genetic technology").

Within the European Union (and in Italy), the principle of freedom of enterprise holds; consequently, there is no absolute prohibition on producing genetically modified foodstuffs and placing them on the market (see above, section "Use of GMO in food production"). However, all the distinct operations involved in the production of HM foodstuffs are governed by European Union rules (see above, section "Outline of the relevant law") in order to ensure food safety (see above, section "Food security") by means of specific authorisations (see above, the entire part "Admission") which must comply with the precautionary principle (see above, section "Legal superstructure") and with the principle of substantial equivalence between the GM product and the traditional product. The rationale for these rules is that the important issue in GMO foodstuff production is not so much the "product" as, rather, the procedure, which is different from that of natural crossing or recombination (see above section "Use of GMO in food production")

At the moment of making a purchase, consumers always find themselves facing a risk, inherent in any choice. The same holds true for choice of foodstuffs; therefore it is crucial for consumers to be enabled to acquire proper and in-depth information on what they intend to eat. For this reason, it is compulsory for the food label to indicate the presence of GMOs if these have been utilised in the production process (see above, section "Labelling regime").

The liability for damage caused by consumption of GM foodstuffs may involve the sphere of public law (in which case the penalties for failure to comply with the requirements imposed by the rules on GMOs are established by the individual Member States, given the absence, within the European Union, of competence in criminal matters) or the sphere of private law (see above, section "Liability"). Civil liability may concern the damage caused by a given farmer's GM crops to the traditional or organic crops grown by a neighbouring farmer (see above, section "Genetic technology"), or the damage inflicted on the individual consumer of GM foodstuffs. In the latter case, Community rules on liability for damage caused by a defective product can be invoked (see above, section "Product liability").

Some Useful Clarifications

As additional information, in our view the following observations will prove useful:

In some subject-areas, risk management[29] is beginning to exert a greater impact on the public authorities' decision-making process. The formulation and implementation of government policies pertaining to certain subjects involve complex interac-

[29] On this subject see above all the work of the German sociologist, Ulrich Beck.

tion between scientific and technological questions. Therefore the juridical bodies entrusted with drawing up the legal aspects of the rules often need to consult with scientific experts who are in possession of in-depth knowledge on the subject, or they may need to call upon advanced technical analyses. On the basis of the information thereby acquired, one of the distinct opinions on the matter at hand will be selected, and will thus become the legally binding rule.

In contrast to the technocratic character of many of the current Community rules, there is a desire for greater openness of the decision-making processes to all components of society. This would allow a broader base of opinion to make a contribution to formation of the rules and to an improvement in the quality of the decisions. In other words, the overall framework of the European Union is experiencing a demand for critical revision of the system of European governance, in the direction of its democratisation.

Similar developments are making themselves felt with regard to GMOs, in which intervention by European law-making authorities in the production of rules, and also by Community institutions (Commission and EFSA) in decisions concerning authorisations, is beginning to clash with a profound feeling of scepticism among European citizens towards the political-institutional apparatus of the Union. At the same time, there is considerable worry among citizens with regard to the possible risks that GMOs could involve for the environment and human health.

In evaluating foodstuffs, and with regard to consumers' demand for an opportunity to become involved by democratic participation in rulings and decisions pertaining to GMOs, it is appropriate to take note both of article 9 of Directive 2001/18, which refers to consultation of the public and making information available to the public,[30] and also of article 24 of the same Directive on the opportunity for citizens to express their opinion with regard to a GM product for which authorisation has been requested.[31] The provisions are confirmed by articles 9 and 10 of Regulation

[30] Article 9 of the Directive 2001/18: "*Consultation of and information to the public*. 1. Member States shall, without prejudice to the provisions of Articles 7 and 25, consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time period, in order to give the public or groups the opportunity to express an opinion.// 2. Without prejudice to the provisions of Article 25: – Member States shall make available to the public information on all part B releases of GMOs in their territory; – the Commission shall make available to the public the information contained in the system of exchange of information pursuant to Article 11".

[31] Article 24 of the Directive 2001/18: "*Information to the public*. 1. Without prejudice to Article 25, upon receipt of a notification in accordance with Article 13(1), the Commission shall immediately make available to the public the summary referred to in Article 13(2)(h). The Commission shall also make available to the public assessment reports in the case referred to in Article 14(3)(a). The public may make comments to the Commission within 30 days. The Commission shall immediately forward the comments to the competent authorities.// 2. Without prejudice to Article 25, for all GMOs which have received written consent for placing on the market or whose placing on the market was rejected as or in products under this Directive, the assessment reports carried out for these GMOs and the opinion(s) of the Scientific Committees consulted shall be made available to the public. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified".

No. 178/2002 on food safety[32] and, above all, by article 11 of the 2007 Treaty on the European Union concerning what is known as the "participatory democracy provision".[33]

In short, it can be concluded – and this must necessarily be taken into account – that in European Union law, public participation in decision-making processes is guaranteed even in sectors with an elevated technical-scientific content, such as that of GMOs.

[32] Article 9 of the Regulation n. 178/2002: "*Public consultation*. There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it".

Article 10 of the Regulation n. 178/2002: "*Public information*. Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk"..

[33] Article 11 of the Treaty on the European Union: "1. The institutions shall, by appropriate means, give citizens and representative associations the opportunity to make known and publicly exchange their views in all areas of Union action.// 2. The institutions shall maintain an open, transparent and regular dialogue with representative associations and civil society.// 3. The European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent.// 4. Not less than one million citizens who are nationals of a significant number of Member States may take the initiative of inviting the European Commission, within the framework of its powers, to submit any appropriate proposal on matters where citizens consider that a legal act of the Union is required for the purpose of implementing the Treaties.// The procedures and conditions required for such a citizens' initiative shall be determined in accordance with the first paragraph of Article 24 of the Treaty on the Functioning of the European Union".

Part II
National Reports – EFTA

Chapter 7
Genetic Technology and Food Security: Country Report – Norway

Hans Morten Haugen

The Norwegian Gene Technology Act stands out by specifying five concerns. It requires that the gene technology shall not be harmful for human health and the environment, but additionally that deliberate release of genetically modified organisms (GMOs) shall be of benefit to society, ethically justifiable and socially acceptable, and is likely to promote sustainable development. As a member of the European Economic Area (EEA), Norway is in general bound to implement EU directives, but according to EEA Agreement Annex XX (Environment), Article 25.d(c) Norway can apply national legislation relating to GMOs for other concerns than health and environment. The restrictive approach implies that until 2015 no GMOs have been accepted in Norway, but assessments of EU-approved GMOs are under way. While human rights is neither specified in the Gene Technology Act or the Food Act, nor in the constitution, Norway's general policies confirms the right to food.

General Information

Use of GMO in Food Production

Norway is not a member of the EU, but as a member of the EEA, Norway is required to adopt much of the EU legislation. EU regulations on genetically modified food and feed, among them Regulation 1829/2003 on genetically modified food and feed and Regulation 1830/2003 concerning the traceability and labelling are still,

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however, not implemented in Norway.[1] Until implementation of these regulations, Norway has national legislation concerning processed GM food and feed products that are harmonised with the EU legislation. The Norwegian EEA Agreement Annex XX (Environment) Article 25.d(c) gives a basis not to approve living GMOs in Norway that have been approved in the EU. The paragraph reads:

> The Contracting Parties agree that the Directive only covers aspects relating to the potential risks to humans, plants, animals and the environment. The EFTA States therefore reserve the right to apply their national legislation in this area in relation to other concerns than health and environment, in so far as it is compatible with this Agreement.

The Directive that is referred to is Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

Currently, there are no approved GMO in agriculture. The last decision taken was in relation to Monsanto's oil canola line GT73, which was not approved, despite the fact that it is approved in the EU. In November 2014 the Norwegian Ministry of Climate and Environment announced that 9 EU-approved GMOs could also be sold on the Norwegian market on the basis of the EEA overall requirements, as they have been approved by the EU in accordance with directive 2001/18/EC, but they will now be assessed by Norwegian authorities based on the Norwegian 1993 Act Relating to the Production and Use of Genetically Modified Organisms, etc. (Gene Technology Act).

The high requirement for approving GMOs in Norway is based on Article 10 and Article 1 of the Gene Technology Act. The stated purpose of the Act, as specified in Section 1 is to ensure that the production and use of genetically modified organisms and the production of cloned animals take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on health and the environment. Moreover, Article 10, 2nd part reads:

> The deliberate release of genetically modified organisms may only be approved when there is no risk of adverse effects on health or the environment. In deciding whether or not to grant an application, considerable weight shall also be given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development.

This provision has been analyzed by the Norwegian Biotechnology Advisory Board in a 2009 study.[2]

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[1] There are several reasons why the GM regulations 1829/2003 and 1830/2003 are not implemented. GMO issues are political sensitive in Norway, but it must be noted that Norway has made a draft decision which must be accepted by other EFTA/EEA countries (Iceland and Lichtenstein) before EFTA and EU can make a decision in the EEA Joint Committee. If there will be an implementation of the GM regulations in Norway, GM and GMO products approved in the EU will still not be automatically approved in Norway. But it will no longer be necessary to submit separate applications to Norway, because the applications will apply to the whole EEA.

[2] Norwegian Biotechnology Advisory Board, *Sustainability, benefit to the community and ethics in the assessment of genetically modified organisms* (2009); http://www.bion.no/filarkiv/2010/07/2009_11_18_diskusjonsnotat_baerekraft_engelsk.pdf (Feb. 2, 2015).

One of the EU-approved GMOs that will now be assessed, based on the five requirements of the Gene Technology Act (ethics, sustainable development, societal benefit, health and environment), MON810, is for ordinary planting.[3] The November 2014 announcement specifies that in addition to insect resistance, one of the EU-approved GMOs for feed, MON863, contains a gene for antibiotic resistance. On a general note, the 2014 announcement from the Ministry emphasizes that Norwegian feed and food regulations do prohibit GMO products with intact genes for antibiotic resistance. Moreover, these GMOs for feed use cannot be imported for processing, because the approvals only concern living GMOs, i.e. grains. Thus, the range of use in Norway is limited.

As concerns feed for aquaculture fish, the situation has for many years been different. Before 15 September 2005, there were no requirements on the approval of processed (non-living) genetic material. Products that were lawfully placed on the Norwegian marked before the EU regulations 1829/2003 and 1830/2003 entered into force in EU – and still not implemented in Norway – are termed 'existing products'. Such existing products were permitted to be imported in a transitional period of 3 years, provided that a specific notification was sent to the Norwegian Food Safety Authority before 15 March 2006. As the transitional period passed without Norway having implemented the EU Regulations 1829/2003 and 1830/2003, four fish feed companies have applied for an exemption of the authorisation requirements of 19 EU-approved existing products, and the Norwegian Food Safety Authority has granted exemption for a period of 1 year each time. Hence, four producers of fish food have had a permission to import 19 specified processed genetically modified feed – in case there will be a restriction in alternative supply of necessary inputs, but as this situation has not occurred, the four producers have not made use of this permission. According to the Norwegian Food Safety Authority, these four fish feed producers are actively avoiding the use of GM feedstuff. The exemption was not renewed in October 2014, as "there is no real need to use such feed…",[4] based on the fact that the four producers had never made use of the GM feedstuff.

The Norwegian government 2005–2013 was a center-left majority government, and had an explicit position on genetic technology in their platforms, the last being agreed in 2009. It said that the government "remain unchanged on the exception we received in the EEA Agreement stating that the Norwegian authorities shall decide which genetically-modified products may be delayed, marketed and sold in Norway. We shall continue to have a restrictive attitude…" The conservative minority government from 2013 does not say much on genetic technology and biotechnology,

[3] In addition, six GMOs are for feed; and two are flowers; see Norwegian Ministry of Climate and Environment, *Rettslig status for genmodifiserte produkter* [Legal status of genetically modified products] (2014); https://www.regjeringen.no/nb/aktuelt/Rettslig-status-for-genmodifiserte-produkter/id2342458/?regj_oss=20 (Feb. 2, 2015).

[4] Norwegian Food Safety Authority, Bakgrunn for avslag om å bruke genmodifisert fiskefôr [Background for rejection of application on the use of genetically modified feed] (2014); www.mattilsynet.no/planter_og_dyrking/genmodifisering/bakgrunn_for_avslag_om_aa_bruke_genmodifisert_fiskefor.16613 (Feb. 2, 2015).

except from "Introduce the polluter pays principle in the aquaculture industry."[5] Pollution is regulated in the Aquaculture Act, as outlined in section "Outline of the relevant law" below.

Representatives of both parties of the government are cautiously in favour of allowing GMOs, but the representative of the Progress Party specifies that initially this can be limited to GM feedstuff.[6] The current Minister for Agriculture and Food has confirmed, however, that the Government will maintain the restrictive position of previous governments regarding use of GMOs in Norway.[7] Together with the Labour Party, that voted in favour of implementing the EU biotechnology directive 98/44/EC, but that has a similarly cautious approach to GMOs and GM food and feedstuff, the two government parties constitute more than ¾ of all representatives in the Parliament. The five other opposition parties, constituting less than ¼ of all representatives, are generally opposing both living GMOs and GM food and feedstuff in Norway.

While Norwegians are on average more positive to genetic technology than the average in the EU, there is still an overwhelmingly negative attitude against GM food in Norway.[8]

Food Security

Norway is not having its own definition of food security, but refers to the international instruments and the 1996 Food Summit's definition of food security. Norway was actively contributing to the negotiations of the 2004 Voluntary Guidelines to Support the Progressive Realization of the Right to Food in the Context of Food

[5] Government of Norway, *Political platform for a government formed by the Conservative Party and the Progress Party* 31 (2013); https://www.regjeringen.no/nb/dokumenter/politisk-plattform/id743014 (Feb. 2, 2015). It also says – at p 45 – that it will "...initiate an evaluation of the biotechnology law…", but from the context where it appears, this will primarily apply to medical use for human beings.

[6] For the various parties' positions (in Norwegian), as expressed in the Parliament in 2013; http://www.stortinget.no/no/Saker-og-publikasjoner/Publikasjoner/Referater/Stortinget/2011-2012/120319/1 (Feb. 2, 2015).

[7] *Nationen*, Listhaug sier nei til GMO [Listhaug says no to GMOs] (2014); http://www.nationen.no/landbruk/listhaug-sier-nei-til-gmo/ (Feb. 13, 2015); see also *supra* note 24 for a recent decision in the Norwegian Parliament, adopted unanimously.

[8] For a summary of the Eurobarometer 2010 survey (EB 73.1) (presented in Norwegian, but with easily readable graphs), see: Torben Hviid Nielsen, Holdninger til bioteknologi: Nye vinder? 21 Gen*ialt* 12–13 (2012); http://www.bion.no/filarkiv/2012/06/GENialt_3_2012web.pdf (Feb. 2, 2015). (Moreover, in a survey undertaken by the Norwegian Agricultural Economics Research Institute (NILF) in 2011, less than 15 % of those surveyed agreed that cheap food is more important than animal welfare, food safety and food taste, while 85 % of respondents disagreed. (Moreover, 70 % said that adequate access to food, lively villages, environmentally friendly production, beautiful landscape and a reasonable salary for the farmers, are all more important than cheap food.)

Security, which does not explicitly approve of GMO in agriculture. In the WTO negotiations, Norway has promoted an understanding of the multifunctional dimensions of agriculture.[9] Food safety is seen as an essential and integral component of food security, and the Norwegian Food Safety Act is the most comprehensive food-related legislation.

There is no recognition of the right to food in the Norwegian Constitution. A proposal for including economic, social and cultural rights in the Norwegian Constitution included the right to food as one of the elements in the right to an adequate standard of living.[10] The Parliamentary approval of a new human rights chapter in the Norwegian Constitution in 2014 did not result in provisions on the right to health, food or an adequate standard of living – but the provision on children's rights says that children have the right to protection, including of their "economic, social and health security…"[11]

Legal Superstructure

The relationship to the EU/EEA is described above. Norway still has not implemented the EU Regulations. For living GMOs, Norway is a party to the Cartagena Protocol, and the relevant EU regulations, law and national regulations are listed in its interim report to the Biosafety Clearing House.[12] Two regulations under the 1993 Gene Technology Act have been translated into English: the 2005 Regulations relating to impact assessment pursuant to the Gene Technology Act[13] and the 2005 Regulations relating to the labelling, transport, import and export of genetically modified organisms.[14]

Moreover, for non-living GMOs, there are a wide range of regulations under the 2003 Act relating to food production and food safety, etc. (Food Act), the most

[9] Government of Norway, *Multifunctional agriculture – the case of Norway* (2002); http://www.regjeringen.no/upload/LMD/Vedlegg/Brosjyrer_veiledere_rapporter/179755-multifunc_red.pdf (Feb. 2, 2015).

[10] Norwegian Parliament, *Dokument 12:31 (2011–2012) Grunnlovsforslag fra Per-Kristian Foss, Martin Kolberg, Marit Nybakk, Jette F. Christensen, Hallgeir H. Langeland, Per Olaf Lundteigen, Geir Jørgen Bekkevold og Trine Skei Grande* 5; for alternative proposals; see also p 10 and p 11 (2012).

[11] Norwegian Constitution, Section 104; https://www.stortinget.no/Global/pdf/Constitutionenglish.pdf?epslanguage=no (Feb. 2, 2015).

[12] Government of Norway, *Interim National Report* 5–6; and Annex 1 (2005); http://www.cbd.int/doc/world/no/no-nr-cpbi-en.pdf (Feb. 2, 2015); the most recent report does not include a similarly detailed list; see Government of Norway, *Second Regular National Report on the Implementation of the Cartagena Protocol on Biosafety* (2011); http://en.biosafetyscanner.org/pdf/doc/478_allegato.pdf (Feb. 2, 2015).

[13] http://www.regjeringen.no/en/dep/md/documents-and-publications/acts-and-regulations/regulations/2005/regulations-relating-to-impact-assessmen.html?id=440455

[14] http://www.regjeringen.no/en/dep/md/documents-and-publications/acts-and-regulations/regulations/2005/regulations-relating-to-the-labelling-tr.html?id=440383

important being the 1983 Foodstuff regulation, the 2014 regulation on food information to the consumers (section "Labelling regime" below) and the 2002 Feed regulation (section "Threshold values" below).

Outline of the Relevant Law

As the Gene Technology Act has been presented in section "Use of GMO in food production" above, the emphasis here will be on the various acts which regulates non-living GMOs and living GMOs, respectively. Concerning the non-living, the most important is the 2003 Food Act, which says in Section 1 (extract):

> The purpose of this Act is to ensure safe and wholesome food, to promote health, quality and consumer concerns along the whole production chain, and to provide for sustainable production.

The Act is also intended to promote sound plant and animal health.

Section 6 (Risk prevention, notification and implementation of measures) applies the phrase "reason to suspect that food may be injurious", specifying immediate obligations on the enterprise to "initiate any necessary measures to prevent, reduce or eliminate any harmful effects; these include stopping sales of products and initiating their withdrawal from the market." Requirements concerning food safety are further specified in Section 16 of the Food Act.

Sections 9–11 mandate the issuing of regulations for product approval, labelling and traceability, with Section 9 also including a possibility of prohibiting the presence of GMO.[15] Sections 18 and 19 is on plant and animal health, respectively.[16]

Turning to living GMOs, three other laws are relating to food resources: the 2009 Nature Diversity Act, the 2008 Marine Resources Act and the 2005 Aquaculture Act. The latter does not include any provisions addressing genetic resources in general or GMOs in particular, but Section 13 (Restoration and recapture obligations) is specifying that anyone involved in aquaculture may be required to recapture any released species. The omission of explicitly addressing GMOs in the aquaculture act must be considered surprising, as there has been considerable debate in Norway on genetic modification of fish.[17] The only case that has been presented before the Norwegian Advisory Board on Ethical Aspects of Patenting was on GMO salmon *(salmo salar)*, that was growing exceptionally fast (patent application no 19933276). Even if the Advisory Board recommended that the application should be rejected –

[15] In line with its restrictive approach, Norway was playing an active role in the Codex Alimentarius, both the task force on biotechnology (TFBT) and Codex Committee on food labelling (CCFL), which have now fulfilled their tasks and have been discontinued.

[16] They both require that "Any person shall exercise due care to avoid any risk…"

[17] Ingrid Olesen, G. Kristin Rosendal, Morten Rye, Morten Walløe Tvedt and Hans B. Bentsen, Who Shall own the Genes of Farmed Fish? in *Global Privatization and Its Impact* (Ingrid J. Hagen and Thea S. Halvorsen eds., 2009).

for reasons of animal welfare, in accordance with the Norwegian Patent Act[18] – the application was later approved by Norwegian patent authorities.[19] The fish was, however, not approved by the Norwegian Environmental Agency. There is very restrictive attitude towards genetically modified animals in Norway, and when genetically modified aquarium fish was found in a pet shop in 2012, this caused strong concern in the Norwegian Environmental Agency.[20]

The 2009 Nature Diversity Act addresses access to genetic material in Chapter VII (Sections 57–61), and the last sentence of Section 57 mandates "appropriate measures for sharing the benefits arising out of the utilisation of genetic material and in such a way as to safeguard the interests of indigenous peoples and local communities." Sections 58–60 are on genetic material from the natural environment, from public collections and from other countries, respectively. Part 2 of Article 60 reads:

> When genetic material from another country is utilised in Norway for research or commercial purposes, it shall be accompanied by information regarding the country from which the genetic material has been received (provider country). If national law in the provider country requires consent for the collection of biological material, it shall be accompanied by information to the effect that such consent has been obtained.

By the formulation "utilised in Norway for research or commercial purposes" this provision covers a wide range of acts, while the similar provision in the Norwegian Patent Act (Section 8 b) only refers to inventions which form the basis for a patent application.[21] As anyone can apply for a patent in Norway through either the PCT system or the EPO system – neither of which have similar requirements as the Norwegian Patent Act – the disclosure obligation is rather weak.

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[18] Section 1 b, part 2, 4 reads (extracts): "the following, in particular, shall not be patentable: … processes for modifying the genetic identity of animals, which are likely to cause them, suffering without any substantial medical benefit to man or animal, including animals resulting from such process."

[19] For a critical report, see the Norwegian Advisory Board on Ethical Aspects of Patenting, *Patentnemnd uten portefølje? En analyse av etiske utfordringer ved patentering* (part of the report is in English] (2008); http://www.etikkom.no/Documents/Publikasjoner-som-PDF/Patentnemnd%20uten%20portef%C3%B8lje%20(2008).pdf (Feb. 2, 2015).

[20] The responsible in the Agency is quoted as saying: "It is serious that genetically modified aquarium fish are imported and sold in this country. No genetically modified animals are approved in Norway, and therefore the sale and keeping of such animals is illegal"; see http://www.nationen.no/2012/11/30/nyheter/gmo/genmodifisering/genmodifisert/fisk/7831505 (Feb. 2, 2015).

[21] Section 8 b reads (extracts): "If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. […] Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 166 [false declaration to public authorities]. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

Turning to the 2008 Marine Resources Act, it specifies in Section 7 (Principle for management of wild living marine resources and fundamental considerations) that it encompasses genetic material derived from such resources, and the principles include:

> a) a precautionary approach, in accordance with international agreements and guidelines,
> b) an ecosystem approach that takes into account habitats and biodiversity,
> c) effective control of harvesting and other forms of utilisation of resources,
> …
> g) ensuring that management measures help to maintain the material basis for Sami culture.

Section 2 of the same Act says that "Wild living marine resources belong to Norwegian society as a whole", and Section 10 says that "a proportion of the benefits arising out of the use of Norwegian marine genetic material shall accrue to the state." It is worth noting that unlike the Convention on Biological Diversity, where the sovereign rights over the natural resources are vested with states, it is the "Norwegian society as a whole" that are to exercise the ownership rights over the marine resources. In addition, the management of living marine resources shall "help to maintain the material basis for Sami culture", as seen above. No specific measures or regulations have been proposed for this purpose. Rather, the overall policies on management of Norwegian marine resources have been criticized for leading to increased commodification and commercialization, with the state selling allocating and selling fishing quotas, but as this is on the side of the overall scope of this analysis, the details of this criticism will not be pursued further.

Admission

Restriction of GMO

There are no legal provisions that explicit mandate GMO-free zones, but Section 14 of the 2005 Aquaculture Act on protection of specific areas reads: "The Ministry may establish a ban, order relocation or place other conditions on aquaculture activities if such actions are necessary to protect areas of special value to aquatic organisms." Moreover, the strict requirements contained in Section 10 of the Gene Technology Act and the comprehensive assessment of the EU approved GMOs, as already noted in section "Use of GMO in food production" above, based on ethics, benefit to society and sustainable development, in addition to assessing risks on human health and the environment.[22] Currently, Norwegian agriculture is GMO-

[22] For the most recent health and environment risk assessments, see Norwegian Scientific Committee on Food Safety, *Endelig helse- og miljørisikovurdering av genmodifisert mais 59122 x NK603* (2014); *Endelig helse- og miljørisikovurdering av genmodifisert mais T25* (2014; considered not to be valid in Norway, according to Ministry for Climate and Environment; *supra* note 3); *Endelig helse- og miljørisikovurdering av genmodifisert mais MON 89034* (2014); and *Endelig*

free. Even if the aquaculture industry were given a permission to import processed genetic material in feed for aquaculture fish this permission has not been utilized.

Concerning genetic modifications and enhancement of fish in aquaculture, the controversies can be illustrated by the public debate when the Norwegian Company Aqua Gene was purchased by German EW Group in 2008. There were strong concerns that this might lead to the EW Group seeking to patent the aquatic genetic material developed by Aqua Gene – with considerable public funding.[23] At the time of the purchase, Aqua Gene was reportedly the largest world market leader in developing salmon and trout.

Admission of GMO in Food Production

As explained above, a separate application must be submitted to Norway regarding processed GM food and feed products. The Norwegian Food Safety Authority is the competent authority for such GM products. Thus, EU approved products containing processed genetic material are not automatically approved in Norway.

For living GMO food and feed products, a separate application to Norway is not necessary. In accordance with the EEA Agreement, Norway must evaluate all GMO applications received by any EU member state, and the final decision is with the Ministry of Climate and Environment, based on a recommendation from the Norwegian Environmental Agency, which also draws upon other agencies' recommendations.

Threshold Values

In accordance with the 2002 Norwegian Feed regulation Section 4, 2nd part and the 1983 Norwegian Foodstuff regulation Section 16a, 2nd part concerning authorisation of GM food and feed, there is an exception from the approval requirement for products containing less than 0.9 % of processed genetic material. The requirements are that the product has been approved by the EU, and that there is an accidental or technically unavoidable presence of processed genetic material, and provided that the enterprise can document such causes for the presence.

Moreover, the Norwegian regulations allow for a presence of 0.5 % GM in imported products in the absence of a EU approval, but only if the genetically modified material has been subject to a risk assessment by either the European Food

helse- og miljørisikovurdering av genmodifisert mais NK603 x MON810 (2014); all available at http://www.vkm.no/faggruppene/faggruppen-for-genmodifiserte-organismer/avsluttede-risikovurderinger (Feb. 2, 2015).

[23] See Olesen et al., *supra* note 17.

Safety Authority or the Norwegian Scientific Committee on Food Safety – and found to be safe, also requiring that the method for analysis is publicly available.

Implementation and Enforcement, Controlling Regime

In accordance with Section 23 of the Food Act, the monitoring and control of food, foodstuff and feed is undertaken by the Norwegian Food Safety Authority, and this Authority has also monitoring functions under the Gene Technology Act.

Labelling Regime

The 2002 Norwegian Feed regulation and the 2014 regulation on food information to the consumers both specify the labelling requirements for food and feed produced from a GMO, as well as for GMO food and feed, in Section 4b first part and Section 4 first part, respectively.

According to the second part of Section 4 of the 2014 regulation on food information to the consumers and the second part of Section 4b, respectively, the labelling requirement does not apply if the content of the processed genetic material in a product is less than 0.9 %, provided that there is an accidental or technically unavoidable presence of authorised processed genetic material.

Liability

Genetic Technology

The 1993 Gene Technology Act says in Section 25 (extracts):

> Any person who wilfully or through negligence contravenes provisions set out in or issued pursuant to this Act or decisions made pursuant to the said provisions is liable to fines or imprisonment for a term not exceeding one year. If there are especially aggravating circumstances, imprisonment for a term not exceeding four years may be imposed.

What is implied by especially aggravating circumstances is not clarified by jurisprudence from domestic courts. It must be considered to be a high threshold for applying part 2 of Section 25.

Section 23 of the same Act (Compensation) reads (extracts):

> Any person responsible for activities pursuant to the present Act is liable to pay compensation regardless of any fault on his part if his activities cause damage, nuisance or loss through the deliberate or unintended release of genetically modified organisms into the environment.

> Moreover, the provisions of Chapter 8 of the Pollution Control Act concerning compensation for pollution damage apply insofar as they are appropriate.

We see that this responsibility is objective and "regardless of any fault on his part…" and that unintended release is also subject to compensation. Section 24 of the same Act is on coercive fines, while Section 20 is on "Order to stop activities" and Section 21 is on "duty to avoid or limit damage". The personal liability must therefore be considered to be strong in the Gene Technology Act.

Product Liability

Section 28 of the 2003 Food Act says that anyone who contraveens the Act wilfully or through gross negligence is (extract):

> Liable to fines or to a term of imprisonment not exceeding one year or both, unless more severe penal provisions apply. Complicity or an attempt is liable to the same penalties. If there are particularly aggravating circumstances, a term of imprisonment not exceeding two years may be imposed.

Section 26 of the 2003 Food Act is on coercive fines, while Section 24 is on "special cleansing and disinfection procedures" and Section 25 is on "closure of premises". Hence, the Food Act provides for rather strong liability.

Similar levels (1 year and 2 years in particularly aggravating circumstances) are also found in the 2005 Aquaculture Act Section 31, and the same Act contains Violation fines (Section 30) and coercive fines/enforcement damages (Section 28).

As the 2008 Marine Resources Act and the 2009 Nature Diversity Act are primarily addressing genetic resources in the wild – the latter also covering genetic material in public samples in Section 59 – they are not considered relevant to introduce under this section of liability when dealing with GMOs.

Summary

While Norway still has a restrictive approach,[24] the future of GMOs in Norway is far from certain. In the realm of food processing, those who make use of imported inputs but seek to avoid GM soy and maize find it increasingly difficult to comply with its own standards. In the realm of aquaculture, the fact that the four fish feed

[24] All political parties in the Norwegian Parliament said in *Innst. 231 S (2014–2015) Innstilling til Stortinget fra Energi- og miljøkomiteen*, adopted 14 April 2015: "The Parliament requests the government to ensure an approval procedure for GMOs which implies that each GMO is assessed under the Gene Technology Act, specifying whether the GMO in question shall be prohibited, before the GMO can be legal to sell in Norway." Two other decisions, one on prohibiting NK603; see *supra* note 22, were made with majority votes. For a general assessment of the Norwegian legislation, see Fauchald, Ole Kristian, Genetically Modified Organisms and Precaution in

companies never had to make use of the exemption allowing them to import feed containing GM feed – leading to the non-continuation of the exemption in 2014[25] – indicates that it is possible to engage in imports-based food processing without encountering GM feed.

Moreover, the concerns that the new government would allow for more GM feed and GMOs in agriculture have not yet come true. The restrictive approach seems to be maintained, illustrated by the fact that the Minister of Climate and Environment said that it was "joyous" [gledelig] when announcing that her Ministry had found that an EU-approved maize was no longer permitted. The Norwegian Scientific Committee on Food Safety had previously found that this maize line did not constitute any risk to human health or the environment.[26]

The pressure from the international companies to have their products approved by European governments will undoubtedly continue, however. The overall assessments of ethics, benefits to society and sustainable development, in addition to risk assessment concerning human health and environment, as found in the Gene Technology Act, do, however, provide Norway with adequate legal tools for the future. Also the other acts analyzed above must be considered adequately robust and comprehensive in order to maintain a restrictive and precautionary approach.

Norwegian Law, in *Implementing the Precautionary Principle: Approaches from the Nordic countries, the EU and USA* (Nicolas de Sadeleer ed., 2007).

[25] Norwegian Food Safety Authority, *supra* note 4.

[26] Norwegian Scientific Committee on Food Safety, *supra* note 22 (on T25). The November 2014 announcement by the Norwegian government, *supra* note 3, said that the approval of this maize line, T25, was no longer valid, but failed to inform that this was due to the expiration of the 10 year approval period. As the new application for approval of T25 was submitted under regulation 1829/2003, which does not yet apply to Norway, see *supra* note 1, it was possible for the Norwegian Government to conclude that it is not valid in Norway.

Chapter 8
Genetic Technology and Food Safety: Country Report – Switzerland

Christoph Errass

Introduction

Shortly after the first genetic modification in 1973,[1] politicians responded. Following various requests from Parliament, the Federal Council answered by invoking the benefits of the new technology and advising to refrain from legal regulation.[2] Self-regulation of science was considered to be sufficient and it was not thought that legal regulation would lead to any significant reduction of risks.[3] In any case, the federal government already possessed rudimentary legislative powers to protect people and the environment from genetic modifications.

On 13th April 1987, the editors of the Swiss magazine "Beobachter", a consumer magazine, filed a popular initiative "against abuses of reproductive and genetic engineering in humans,"[4] with 126'686 valid signatures. The Federal Council

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The following abbreviations are used: Amtliches Bulletin des Ständerats (Official Bulletin of States Council): AB S; Amtliches Bulletin des Nationalrats (Official Bulletin of National Council): AB N; Amtliche Sammlung (Official Collection): AS; Bundesblatt (Federal Bulletin): BBl; Systematische Sammlung (Systematic Collection): SR.

[1] Cf. Christoph Errass, Öffentliches Recht der Gentechnologie im Ausserhumanbereich, Bern 2006, p. 3.

[2] Cf. Errass (FN. 1), p. 21 t seq.

[3] AB N 1982 981.

[4] Cf. Botschaft zur Volksinitiative „gegen Missbräuche der Fortpflanzungs- und Gentechnologie beim Menschen" vom 18. September 1989 (Botschaft Missbräuche), in: BBl 1989 III 989 ff. (= Message to the popular initiative "against abuses of reproductive and genetic engineering in humans," dated 18 September 1989 [Message „abuses"]), in: BBl 1989 III 989.

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submitted to Parliament a direct counter-proposal, recommending that not only the use of human reproductive and genetic material, but also the use of non-human reproductive and genetic material be regulated. It also contained a rudimentary regulatory proposal for the protection of the environment. In the parliamentary procedure the counter-proposal was revised, in particular, a new paragraph 3 was added.[5] As the result of the subsequent referendum of 17th May 1992, article 24^{novies}[6] was added to the Federal Constitution of the Swiss Confederation of 29 May 1874[7] which was in force at the time.[8] This article stipulated that the regulation of genetic engineering must ensure the safety of humans, animals, and the environment, as well as the protection of the diversity of animal and plant species, and must also respect the "dignity of living beings". Based on this, the Environmental Protection Act[9] was supplemented in 1995 with detailed regulations.[10] Previously, the legislator had delegated to the Federal Council the power to restrict or prohibit biotechnological processes for the manufacture or processing of foodstuffs or utility articles (article 9 FSA[11]).

Not long after the vote on Article 24^{novies} oFC, the *Schweizerische Arbeitsgruppe Gentechnologie* (engl. Swiss Working Group on Gene Technology) submitted a federal popular initiative "for the protection of life and the environment from genetic engineering" (Gene Protection Initiative).[12] The controversy between supporters and opponents and the battle for votes was virulent. Finally, on 7th June 1998, the initiative was rejected by 66.7 % voters and by all cantons.[13] Nevertheless, the Gene Protection Initiative has left its imprint on the subsequent legislative process. To facilitate the parliamentary debate on this initiative an expert opinion[14] was obtained to identify gaps in the existing legislation on genetic engineering. Based on this

[5] Cf. AB S 1990, p. 477 et seq., 1991, p. 450 et seq.; AB N 1991, p. 556 et seq. On the history cf. Errass (FN 1), p. 22 et seq. On the genesis in the parliamentarian committees cf. Rainer J. Schweizer, in: Aubert/Eichenberger/Müller/Rhinow/Schindler (Hrsg.), Kommentar zur Bundesverfassung der Schweizerischen Eidgenossenschaft vom 29. Mai 1874 (Kommentar aBV), Basel/Zürich/Bern 1987 ff., N 3 et seq. ad Article 24^{novies}; Peter Krepper, Zur Würde der Kreatur in Gentechnik und Recht, Diss. Bern, Basel 1998, p. 350 et seq.

[6] BBl 1992 V 451, 456.

[7] The old Federal Constitution (oFC; AS 1875 1).

[8] The Federal Constitution of the Swiss Confederation of 29 May 1874 was repealed by Number II para. 1 of Federal Decree of 18 December 1998, in: BBl 1999 162.

[9] Federal Act on the Protection of the Environment (Environmental Protection Act, EPA) of 7 October 1983 (SR 814.01).

[10] Cf. Errass (FN 1), p. 27 et seq.

[11] Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act, FSA) of 9th October 1992 (SR 817.0).

[12] Cf. Botschaft über die Volksinitiative „zum Schutz von Leben und Umwelt vor Genmanipulationen (Gen-Schutz-Initiative)" vom 6. Juni 1996 (= Message on the popular initiative "for the protection of life and the environment from genetic engineering [gene protection initiative]" of 6th June 1996), in: BBl 1995 III 1333 et seq.

[13] Cf. Errass (FN 1), p. 30 et seq.

[14] Cf. Rainer J. Schweizer, Gentechnikrecht. Stand des Gesetzgebungsprozesses zur Gentechnik, Zürich 1996.

expert opinion, a parliamentary initiative, the so-called Gen-Lex-Motion,[15] entrusted the Federal Council with closing the identified gaps. However, the Federal Council mainly proposed changes to the EPA[16] and, as a result, Parliament decided to issue a specific Gene Technology Law.[17,18]

In the meantime, the Federal Constitution of 1874 had been replaced in 1999.[19] The provisions on non-human gene technology are now regulated in Article 120 of the new Federal Constitution:

> **Art. 120** Non-human gene technology
>
> 1. Human beings and their environment shall be protected against the misuse of gene technology.
> 2. The Confederation shall legislate on the use of reproductive and genetic material from animals, plants and other organisms. In doing so, it shall take account of the dignity of living beings as well as the safety of human beings, animals and the environment, and shall protect the genetic diversity of animal and plant species.

During the parliamentary debate on the GTA, another popular initiative was launched, the so-called Moratorium Initiative.[20] It was adopted on 27th November 2005 by the people and all cantons.[21]

The moratorium ended on 27th November 2010,[22] but was then extended on the legislative level a first time to 27th November 2013 [23] and a second time to 31st

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[15] Gen-Lex-Motion: Motion WBK-N (96.3363). Ausserhumane Gentechnologie. Gesetzgebung, in: AB N 1996, 1561.

[16] Cf. Botschaft zu einer Änderung des Bundesgesetzes über den Umweltschutz (USG) vom 1. März 2000 (Botschaft Gen-Lex) (= Message to an amendment of the Environmental Protection Law [EPA] of 1st March 2000 [Message Gen-Lex]), in: BBl 2000 2391 et seq.

[17] Federal Act on Non-Human Gene Technology (Gene Technology Act, GTA) of 21 March 2003 (SR 814.91).

[18] Cf. Errass (FN 1), p. 33 et seq.

[19] Federal Constitution of the Swiss Confederation of 18 April 1999 (SR 101).

[20] Cf. Botschaft über die Volksinitiative „für Lebensmittel aus gentechnikfreier Landwirtschaft" vom 18. August 2004 (Botschaft Moratorium) (= Message on the popular initiative "for foodstuffs from GM-free agriculture" of 18 August 2004 [Message on Moratorium]), in: BBl 2004 4937 et seq.

[21] Cf. BBl 2006 1061 et seq.; Errass (FN 1), p. 40 et seq.; Rainer J. Schweizer/Christoph Errass, in: Ehrenzeller/Schindler/ Schweizer/Vallender (ed.), Die schweizerische Bundesverfassung, Kommentar, 3rd edition, Zürich/St. Gallen/Basel/Genf 2014 (St. Galler Kommentar), Art. 120 N 3 et seq.

[22] Cf. **Art. 197 Ziff. 7 BV** Transitional Provision to Article 120 (Non-human gene technology).

Swiss agriculture shall remain free of gene technology for a period of 5 years following the adoption of this constitutional provision. In particular, the following may neither be imported nor placed on the market:

a. genetically modified plants that are capable of propagation, parts of plants and seeds that are intended for agricultural, horticultural or silvicultural use in the environment;
b. genetically modified animals that are intended for the production of foodstuffs and other agricultural products.

[23] Cf. **Art. 37a GTA** Transitional period for putting genetically modified organisms into circulation.

December 2017,[24] both times by amendments to article 37a GTA.[25] Furthermore, the amendment[26] of the Agriculture Act[27] commits the Federal Council to submit by 30th June 2016 a report providing a methodology for the evaluation of the benefits of genetically modified plants. Additionally, the Federal Council has to evaluate the advantages of genetically modified plants and present the results in a cost-benefit analysis (Article 187d Lagr).

According to a survey of 24th August 2013 conducted by the Federal Technical Institute of Zurich, genetic engineering is a controversial issue in Switzerland. Genetically modified food ranks third on the list of concerns of the Swiss population.[28] In addition, the battle between supporters and opponents over the Gene Protection Initiative has left a great divide – in science, in the general public, in Parliament. Even the Federal Administration itself does not share a uniform position. Furthermore, the proposals of the government and the Federal Administration respectively are regularly tightened by Parliament.[29]

Given this general scepticism, it is of no surprise that until now there have only been very few experimental field releases of genetically modified organisms[30] and only a handful of genetically modified products have been approved.[31] So far, four food products have been approved: three varieties of maize and one of soya.[32]

No authorisations may be granted until 27 November 2013 for putting into circulation genetically modified plants and parts of plants, genetically modified seeds and other plant propagation material and genetically modified animals for agricultural, horticultural or silvicultural purposes. The Federal Council issues the required implementing provisions for this period.

[24] AB N 2012 1707, 2013 537 und AB S 2012 1219 et seq., 2013 366; BBl 2013 2497, 2521 et seq.

[25] For further information cf. Schweizer/Rechsteiner, in: Schweizer/Wildhaber/Rechsteiner, Vorschläge für eine Schweizer Koexistenzordnung, in: Schweizer/Errass/Kohler, Koexistenz der Produktion mit und ohne gentechnisch veränderte Organismen in der Landwirtschaft – Rechtsvergleich sowie Grundlagen und Vorschläge für die künftige Regulierung in der Schweiz, Zürich/St. Gallen 2012, p. 209 et seq., p. 242 et seq. Cf. as well Christoph Errass, Moratorium auf Gesetzesebene für bestimmte Umgangsarten mit bestimmten gentechnisch veränderten Organismen, Kurzgutachten zur verfassungsmässigen Zulässigkeit und Gesetzesvorschlag, Bern 2008, not published, passim.

[26] In force since 1st January 2014.

[27] Federal Law on Agriculture (LAgr) of 29th April 1998 (SR 910.1).

[28] Cf. http://www.srf.ch/news/schweiz/wovor-haben-sie-angst

[29] First example: Gen-Lex (cf. Errass [FN 1], p. 33 et seq.); second example: Article 187d LAgr and Article 37a GTA (in the version of 22 March 2013).

[30] Two applications were rejected, five approved (cf. http://www.bafu.admin.ch/biotechnologie/01756/08902/index.html?lang=de)

[31] Cf. http://www.bafu.admin.ch/biotechnologie/01760/08936/index.html?lang=de: As feed three maize varieties and one soya as well as immune biological medicinal products for veterinary use respectively a vaccine for cats or rather horses.

[32] Cf. http://www.blv.admin.ch/themen/04678/04817/04833/04840/index.html?lang=de

Overview of Legal Framework

Constitutional Foundations

Genetic engineering is used in various fields.[33] Actions involving genetic engineering are always taking place under the protection of fundamental rights, including the protection of academic freedom (article 20 FC), the economic freedom (article 27 FC) and the guarantee of ownership (article 26 FC). They can, however, be restricted for different reasons, inter alia for reasons of public interest or the protection of fundamental rights of third parties (article 36 para. 2 FC). According to articles 3 and 42 FC, a constitutional competence is required for the Confederation to enact regulations. This fundamental constitutional competence is enshrined in the aforementioned article 120 FC. There are additional federal competences,[34] such as those provided in article 74 FC on environmental protection and in article 118 FC on health protection.

According to article 120 para. 1 FC, human beings and their environment shall be protected against the misuse of gene technology. Only abuse, i.e. only "excrescence of genetic engineering" (*German*: "Auswüchse der Gentechnologie")[35] should be banned. Article 120 para. 2 FC provides the following criteria which have to be taken into account: the dignity of living beings,[36] the safety of human beings, animals and the environment,[37] as well as the protection of the genetic diversity of animal and plant species.[38,39] Other criteria of abuse could be the granting of patents or the contamination of property of others, even if these acts are *not* hazardous for the environmental and human health.[40] The focus of legislation should be the protection of human beings (both their life and health) and the environment.[41] Although it is not explicitly stated, Article 120 FC also includes the protection of property.[42]

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[33] Cf. Errass (FN 1), p. 5 et seq.; Marcel Brülhart, Gentechnik und Haftpflicht, Bern 2003, p. 5 et seq.

[34] Cf. Errass (FN 1), p. 44 et seq.

[35] Bundesrat Koller (AB N 1991 599).

[36] A comprehensive discussion see Christoph Errass, 20 Jahre Würde der Kreatur, ZBJV 2013, p. 187 et seq.; Errass (FN 1), p. 59 et seq.; Schweizer/Errass (FN 21), N 18 et seq. ad Article 120; Giovanni Biaggini, Kommentar zur Bundesverfassung der schweizerischen Eidgenossenschaft, Zürich 2008, Art. 120 N 6; Jean-François Aubert, in: Aubert/Mahon, Petit commentaire de la Constitution fédérale de la Confédération suisse du 18 avril 1999, Art. 120 N 9.

[37] Errass (FN 1), p. 72 et seq.; Schweizer/Errass (FN 21), N 20 et seq. ad Article 120.

[38] Errass (FN 1), p. 80 et seq.; Schweizer/Errass (FN 21), N 23 et seq. ad Article 120.

[39] Cf. also Astrid Epiney/Bernhard Waldmann/Magnus Oeschger/Jennifer Heuck, Die Ausscheidung von gentechnikfreien Gebieten in der Schweiz de lege lata et de lege ferenda. Unter besonderer Berücksichtigung der Rechtslage in der EU, Zürich/St. Gallen 2011, p. 73 et seq.

[40] Cf. Errass (FN 1), p. 48 et seq.

[41] Cf. Errass (FN 1), p. 53 et seq.; Schweizer/Errass (FN 21), N 11, 13 ad Article 120.

[42] Cf. Errass (FN 1), p. 53 et seq.; Schweizer/Errass (FN 21), N 12 ad Article 120; differing opinion: Epiney/Waldmann/Oeschger/Heuck (FN 39), p. 106.

All objects of protection are both indirectly and directly protected. In order to achieve the protection set out in Paragraph 1, the Confederation shall legislate on the use of reproductive and genetic material from animals, plants and other organisms, thus covering the handling of non-human reproductive and genetic material. This leads to the consideration of foodstuffs, our current topic and the use of therapeutic agents, i.e. organisms that are considered equivalent to chemicals (article 2 Chem), agricultural means of production (article 160 LAgr), genetically modified pathogenic organisms (communicable, wide spread or particularly dangerous human and animal diseases [Article 118 para. 2 lit. b FC]), clinical trials of somatic gene therapy or with grafts of genetically modified animals.[43] In the domain of genetically modified foods not only the safety of humans must be protected but also the dignity of creation of plants and animals must be respected. This will be explained in more detail below when discussing the specific article.

Article 118 FC enshrines the constitutional competence to protect *health* when handling products:

Art. 118 Health protection

1. The Confederation shall, within the limits of its powers, take measures for the protection of health.
2. It shall legislate on:
   a. the use of foodstuffs as well as therapeutic products, narcotics, organisms, chemicals and items that may be dangerous to health;
   b. the combating of communicable, widespread or particularly dangerous human and animal diseases;
   c. protection against ionising radiation.

Article 118 para. 2 lit. a FC is the basis for the Confederation to enact the FSA. The legislator is obliged to adopt the necessary regulations on food that may be dangerous to health. The level of regulation is determined by the danger for the general public, rather than the scientists.[44] In this respect it is a consumers' provision.[45] Article 118 FC is in fact merely a competence to regulate without material instructions.

Foodstuffs, offered in the market place, must not damage the environment. Article 74 FC provides the necessary constitutional basis for federal regulations.[46] It is, contrary to article 118 FC, the basis for regulations to protect against indirect damage, including damage through foodstuffs, for example human excretion after consumption of food. A known issue in the field of medical agents is the residues of birth control pills ingested in drinking water, which lead to a feminization of men

[43] Cf. Errass (FN 1), pp. 238, 243–277.

[44] See Tomas Poledna, in: St. Galler Kommentar (FN 21), Art. 118 N 10; Biaggini (FN 36), Art. 118 N 7.

[45] See Poledna (FN 44), Art. 118 N 10.

[46] See Errass (FN 1), p. 89 et seq.

and fish.[47] Article 74 FC then introduces the precautionary and polluter pays principle even if the wording lacks the necessary clarity.[48] It reads:

> **Art. 74** Protection of the environment
>
> 1. The Confederation shall legislate on the protection of the population and its natural environment against damage or nuisance.
> 2. It shall ensure that such damage or nuisance is avoided. The costs of avoiding or eliminating such damage or nuisance are borne by those responsible for causing it.
> 3. The Cantons are responsible for the implementation of the relevant federal regulations, except where the law reserves this duty for the Confederation.

Also relevant is article 97 FC (Consumer protection), according to which the Confederation shall take measures to protect consumers.[49]

International Law

National food law (on genetically modified organisms) is also influenced by international law, first by fundamental rights (article 11 UN Pact I[50]), then by regulations for ensuring plant genetic resources, through safety regulations (Codex Alimentarius; Cartagena Protocol), and finally by trade regulations (WTO, FTA 1972). Switzerland also has bilateral agreements with the EU (see below section "Authorisation of foodstuffs"). The following paragraphs contain a short presentation of the essential features of the relevant international law.

According to article 11 para. 1 *UN Pact I* the States Parties to the present Covenant recognize the right of everyone to an adequate standard of living for himself and his family, including adequate food, clothing and housing, and to the continuous improvement of living conditions. The States Parties will take appropriate steps inter alia to ensure the realisation of this right. The States Parties to the present Covenant, recognising the fundamental right of everyone to be free from hunger,[51]

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[47] See http://www.reach-info.de/endokrin.htm; EAWAG/BUWAL, Stoffe mit endokriner Wirkung in der Umwelt, Bern 1999; Georg Karlaganis/Christof Studer/Andreas Weber: Xenobiotika mit endokriner Wirkung in der Umwelt. Hysterie oder echte Gefahr?, in: Umweltwissenschaften und Schadstoff-Forschung (UWSF) 1996, 221.

[48] Errass (FN 1), p. 94 et seq.; Alain Griffel, Die Grundprinzipien im schweizerischen Umweltrecht, Zürich 2001, 56; Reto Morell/Klaus A. Vallender, in: St. Galler Kommentar (FN 21), Art. 74 N 20 et seq., 28 et seq.

[49] See Christoph Errass, Elemente zum Verständnis von Art. 7 GTG. Auslegung des schweizerischen Rechts einschliesslich gewisser völkerrechtlicher Bestimmungen, in: Schweizer/Errass/Kohler (FN 25), p. 107 et seq., 175; Epiney/Waldmann/Oeschger/Heuck (FN 39), p. 82 et seq.

[50] International Covenant on Economic, Social and Cultural Rights (SR 0.103.1).

[51] Cf. Christine Breining-Kaufmann, Hunger als Rechtsproblem – völkerrechtliche Aspekte eines Rechtes auf Nahrung, Zürich 1991, passim, in relation to Art. 11 UNO Pact I, p. 59 et seq. See also Marco Borghi/Letizia Postiglione Blommestein (eds.), For an effective Right to adequate food, Freiburg 2002; Marco Borghi/Letizia Postiglione Blommestein (eds.), The right to adequate food and access to justice, Geneva/Zürich/Basel/Bruxelles 2006; Christophe Golay/Melik Özden, Le

shall take individually and through international co-operation, the measures which are needed inter alia to improve methods of production, conservation and distribution of food. Article 11 of UN Pact requires governmental measures[52] but does not grant citizens any[53] justiciable right to food. With Article 12 FC the legislator has created a legally enforceable "Right to assistance when in need", which implements Article 11 of UN Pact I. Article 12 FC stipulates: persons in need and unable to provide for themselves have the right to assistance and care, and to the financial means required for a decent standard of living. Thus, concrete requirements for the handling of genetically modified organisms can be derived neither from article 11 of UN Pact I or from article 12 FC. The *international treaty on plant genetic resources for food and agriculture*[54] has a similar aim as article 11 para. 2 UN Pact I and as such does not provide requirements for handling GMO either. However, it provides evidence that it may be an advantage to cultivate conventional alongside genetically modified organisms. According to recital 6 of the treaty, plant genetic resources for food and agriculture are the essential raw materials for adapting to unpredictable environmental changes and future human needs. Therefore, the parties shall develop and maintain appropriate policy and legal measures that promote the sustainable use of plant genetic resources for food and agriculture. These include the conservation of intra- and inter-specific variations and the expanded use of local and locally adapted crops, varieties and underutilised species. The aim is to obtain a wide range of plant genetic resources to protect food security.[55]

In addition, national food law is influenced by the *Codex Alimentarius Commission*, which provides a global structure formation for international administrative law.[56] The Codex Alimentarius Commission, established by FAO and WHO in 1963 develops harmonised international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in the food trade. The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organisations.[57]

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droit à l'alimentation, Geneva 2006; Gregor T. Chatton, Vers la pleine reconnaissance des droits économiques, sociaux et culturels, Geneva/Paris (Dec. 2013), pp. 245, 291–308, see also p. 196 et seq.

[52] See Jörg Künzli/Walter Kälin, Die Bedeutung der UNO-Paktes über wirtschaftlichem, soziale und kulturelle Rechte für das schweizerische Recht, in: Kälin/Malinverni/Nowak, die Schweiz und die UNO-Menschenrechtspakte, 2. Aufl., Basel/Frankfurt a.M./Bruxelles, 1997, p. 105 et seq., p. 127 et seq., 133.

[53] Differing opinion Künzli/Kälin (FN 52), p. 127.

[54] SR 0.910.6.

[55] See Errass, Element (FN 49), p. 188 et seq.

[56] See Eberhard Schmidt-Assmann, Die Herausforderung der Verwaltungsrechtswissenschaft durch die Internationalisierung der Verwaltungsbeziehungen, Der Staat 2006, p. 315 et seq., p. 321 et seq.

[57] Cf. comprehensively Tilman Makatsch, Gesundheitsschutz im Recht der Welthandelsorganisation (WTO). Die WTO und das SPS-Übereinkommen im Lichte von Wissenschaftlichkeit, Verrechtlichung und Harmonierung, Berlin 2004, p. 204 et seq.; Hans Christian Röhl, Internationale Standardsetzung, in: Möllers/Vosskuhle/Walter (eds.), Internationales Verwaltungsrecht, Tübingen 2007, p. 319 et seq., p. 329 et seq.

The standards adopted by the Codex Alimentarius Commission are non-binding recommendations (soft law). They become national law by incorporation or reference.[58] In relation to genetically modified food, Swiss law does not refer to the provisions of the Codex Alimentarius Commission. However, through article 3 of the Agreement on the application of sanitary and phytosanitary measures,[59] the standards of the Codex Alimentarius Commission have now gained increased validity.[60]

The objective of the *Cartagena Protocol on Biosafety*[61] is to ensure an adequate level of protection with regard to the transfer, handling and use of genetically modified organisms.[62] The focus is on the cross-border movement of genetically modified organisms. Therefore, a core element of the protocol is a procedure by which a transboundary movement of genetically modified organisms should be regulated that does not damage the environment: the Advance Informed Agreement Procedure (AIA procedures; Cart. Prot. Article 7 et seq),[63] a method to ensure prior informed consent. In principle, this method refers only to genetically modified organisms, which are to be introduced into the environment. Food and feed, whether they are genetically modified organisms, or derived from such, are subject to a special procedure under article 11 Cart. Prot (article 7 para. 2 and 3 Cart. Prot.). The core of that process is a "risk assessment".[64] This also applies to living modified organisms intended for direct use as food or feed, or for processing (article 11 para. 1 in conjunction with Annex II lit. j in conjunction with Annex III Cart. Prot.). The risk assessment requires two steps: first, fact-finding and then an evaluation. The risk assessment thus contains a descriptive and a normative component. The risk is to be assessed taking into account the precautionary principle.[65] According to article 11 para. 4 Cart. Prot., a party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its

[58] See Makatsch (FN 57), p. 215 et seq.; Röhl (FN 57), p. 331.

[59] Appendix 1A.4 of the agreement establishing the world trade organization (SR 0.632.20).

[60] See Makatsch (FN 57), p. 218 et seq.; Röhl (FN 57), p. 331; Rudolf Streinz, Rechtliche Aspekte, in: Sturma/Lanzerath/Heinrichts (Hrsg.), Gentechnik in der Lebensmittelproduktion. Naturwissenschaftliche, rechtliche und ethische Aspekte, Freiburg im Breisgau 2011, p. 57 seq., 84.

[61] Prot.Cart.; SR 0.451.431.

[62] Siehe dazu auch Errass, Elemente (FN 49), p. 185 et seq.

[63] See Martin Scheyli, Das Cartagena-Protokoll über die biologische Sicherheit zur Biodiversitätskonvention, ZaöRV 2000, p. 771 et seq., p. 785 et seq.; Mackenzie Ruth/Burhenne-Guilmin Françoise/La Viña Antonio G.M./Werksman Jacob D., in cooperation with Ascencio Alsonso/Kinderlerer Julian/Kummer Katharina/Tapper Richard, An explanatory Guide to the Cartagena Protocol on Biosafty, IUCN Environmental Policy and Law Paper No. 46, Gland/Cambridge 2003, p. 63 et seq.; Katja Loosen, Das Biosafety-Protokoll von Cartagena zwischen Umweltvölkerrecht und Welthandelsrecht, Berlin 2005, p. 6 et seq.

[64] See Scheyli (FN 63), p. 785 et seq.

[65] See recital 4 (Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development) und Art. 11 Abs. 8 Cart.Prot.; Errass, Element (FN 49), p. 186 with further references.

domestic regulatory framework that is consistent with the objective of the Protocol. Switzerland has made use of this option and adopted the Cartagena Ordinance.[66] Genetically modified foodstuffs also fall under this ordinance.[67] With regard to import, article 5 para. 1 CartO refers to the authorisation requirement and the authorisation procedure according to article 25 Release Ordinance.[68,69] In addition, special duties of care are to be observed and accompanying documentation must be delivered (articles 3 and 4 CartO).[70]

The agreement establishing the *World Trade Organisation* has significant impact on food law, in particular through the SPS Agreement and TBT Agreement.[71] We have already discussed the link between SPS and the Codex Alimentarius. This applies particularly to genetically modified foods as is shown by the detailed comment of the U.S. on the WTO-notification[72] and the WTO dispute settlement panel report (dispute settlement WT/DS 291, WT/DS 292 and WT/DS 293 [European Communities — Measures Affecting the Approval and Marketing of Biotech Products]) of 29th September 2006 which shows that the panel considered the de-facto moratorium of the EU inadmissible according to WTO law. Therefore, the multiple extension[73] of the above mentioned moratorium always required special justification.[74]

In addition, the *General Agreement on Tariffs and Trade* 1994 (GATT) must be taken into account.[75] This raises the question of whether genetically modified organisms are equivalent to non GM products in accordance with article III of the GATT. This question raises a controversy that has not yet been answered. Restrictions of certain genetically modified products also fall under the SPS and TBT Agreement. Both agreements prohibit technical, sanitary and phytosanitary measures that create unnecessary barriers to international trade, taking into account that the SPS

[66] Ordinance on the Transboundary Movements of Genetically Modified Organisms of 3rd November 2004 (CartO; SR 814.912.21).

[67] Art. 1 CartO.

[68] Ordinance on the Handling of Organisms in the Environment of 10th September 2008 (RO; SR 814.911).

[69] In more detail see text below under FN 143.

[70] See Errass (FN 1), p. 276 et seq.

[71] Agreement on technical barriers to trade=Appendix 1A.6 of the agreement establishing the world trade organization (SR 0.632.20).

[72] See Bericht über das Ergebnis der EFTA- und WTO-Notifikationen des Entwurfs vom 1. März 2000 zu einer Änderung des Umweltschutzgesetzes vom 30 August 2000 (= Report on results of the EFTA and WTO notifications of the draft of 1 March 2000 on an amendment of the Environmental Protection Act of 30 August 2000), in: BBl 2000 5029.

[73] See text above at FN 25.

[74] Cf. Message on Moratorium (FN 20), p. 4937, 4948 et seq.; Botschaft zur Änderung des Gentechnikgesetzes (Verlängerung des GVO-Moratoriums in der Landwirtschaft [Botschaft Moratorium]) vom 1. Juli 2009 (= Message on the amendment of the Genetic Engineering Act [extension of the moratorium on GMOs in agriculture (Message on Extension)] of 1 July 2009), in: BBl 2009 5435, p. 5458 et seq.

[75] SR 0.632.20.

Agreement is familiar with the precautionary principle. In 2009, the Federal Council was not able to establish conclusively whether or not the moratorium on genetically modified propagating plant material in agriculture was compatible with the WTO law[76] – this doubt still holds true today. In addition, it is likely that labelling schemes also have to comply with WTO law[77]; and in this regard it is worth mentioning that there are potential conflicts between the Cartagena Protocol and international trade laws and these do not have to be decided in favour of the latter. Both agreements are of equal validity, thus a balance of interests must be found.[78] In addition, it must be taken into account that the WTO has yet to answer some key questions, i.e. on cultural relativity of risk assessments including the application of the precautionary principle, on democracy, on public versus scientific rationality. This may be due to the fact that the appellate body of the WTO is aware that such a decision could exceed their functional boundaries and that any enforcement of cultural homogeneity could be seen as an imperialist act.[79]

Agreements Between Switzerland and the EU

Switzerland is not a member of the EU but is a close affiliate.[80] Already on 22nd July 1972 Switzerland had negotiated an free trade agreement with the European Economic Community.[81] This Agreement touches inter alia some[82] legal issues on food, in particular the Protocol[83] N° 2 of 22nd July 1972 concerning certain processed agricultural products.[84] According to article 13 of this Agreement, no new quantitative restriction on imports (from 1st January 1973) or measures having equivalent effect (from 1st January 1975) could be introduced in trade between the

[76] See Message on Extension (FN 74), 5458.

[77] See Streinz (FN 60), p. 85.

[78] Thereto Loosen (FN 63), passim; Jan Neumann, Die Koordination des WTO-Rehts mit anderen völkerrechtlichen Ordnungen, Berlin 1994, p. 112 et seq., in particular p. 250 et seq. (Cart.Prot.).

[79] See Arno Scherzberg, Risikomanagement vor der WTO. Zum jüngsten Handelsstreit zwischen der Europäischen Union und den Vereinigten Staaten über den Umgang mit gentechnisch veränderten Organismen, ZUR 2005, pp. 1, 7–8 with further references; Matthias Herdegen, Informalisierung und Entparlamentarisierung politischer Entscheidungen als Gefährdungen der Verfassung?, VVDStRL 62 (2003), p. 7 et seq., p. 24 et seq.

[80] See Stephan Breitenmoser/Robert Weyeneth, Europarecht. Unter Einbezug des Verhältnisses Schweiz – EU, 2. Aufl. Zürich/St. Gallen 2014, p. 179 et seq.

[81] SR 0.632.401.

[82] In detail and with further references Urs Klemm/Dirk Trüten, Regelungsrahmen im Schweizer Lebensmittelrecht, in: Weber/Klemm/Baumgartner/Uebe/Trüten, Lebensmittelrecht EU – Schweiz, edition 2012, p. 136 et seq., p. 158 et seq.; Rudolf Streinz, Die Europäisierung des Lebensmittelrechts unter Berücksichtigung der Auswirkungen auf die Schweiz, in: Poledna/Arter/Gattiker (ed.), Lebensmittelrecht, Bern 2006, p. 151 et seq., 200.

[83] SR 0.632.401.2.

[84] Thereto Breitenmoser/Weyeneth (FN 80), p. 170 et seq.

European Community and Switzerland. As long as there are different legal regimes between the EU and Switzerland with different effects, the possibility remains to violate article 13 of the FTA. In principle, however, both legal regimes are equivalent, if not identical, in relation to genetically modified food. In many cases Swiss law refers to[85]or incorporates European law without mentioning it specifically.[86] In connection with the above mentioned moratorium the question is raised, however, if it violated article 13 of the free trade agreement.[87]

In addition, several bilateral agreements exist between the EU and Switzerland: the so called Bilateral I[88] and Bilateral II.[89,90] The Conformity Assessment Agreement[91] and the Agreement on Agriculture[92] are both relevant to foodstuffs – the relevance is, however, limited.[93] The Agreement on Agriculture leads to a liberalisation of trade for cheese and to tariff reductions for several other agricultural products as well as to a reduction of the technical trade barriers by mutual recognition of the equivalent legislation on these products.[94] The Bilateral II entails a further extension[95] (adaptation of Protocol N° 2 of the Free trade Agreement).[96] Although the Agreement on Agriculture provides in article 5 of Annex 6 a liberalisation of seeds, paragraph 3 explicitly excludes genetically modified varieties.

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[85] On the European law in relation to genetically modified food see Streinz (FN 60).

[86] Article 16 para. 2 and Article 17 para. 6 GTA for example that apply in particular to food refer on the international recommendations and foreign trade relations, meaning according to the parliamentarian debate the EU law (see Errass [FN 1], p. 185 FN 969, p. 288). See also Streinz, Europäisierung (FN 82), p. 200 et seq., 210.

[87] See Message on Extension (FN 74), 5459; Message on Moratorium (FN 20), 4950.

[88] For a survey see Breitenmoser/Weyeneth (FN 80), p. 171 et seq.

[89] For a survey see Breitenmoser/Weyeneth (FN 80), p. 184 et seq.

[90] See also Streinz, Europäisierung (FN 82), p. 201 et seq.; Tobias Jaag, Europarecht. Die europäischen Institutionen aus schweizerischer Sicht, 3rd edition, Zürich 2010, p. 404 et seq.

[91] Agreement between the Swiss Confederation and the European Community on mutual recognition of conformity assessments of 21 June 1999 (SR 0.946.526.81).

[92] Agreement between the Swiss Confederation and the European Community on trade with agricultural products of 21 June 1999 (SR 0.916.026.81). Thereto Richard Senti, Abkommen über den Handel mit landwirtschaftlichen Erzeugnissen, in: Thürer/Weber/Zäch (eds.), Bilaterale Verträge Schweiz – EU. Ein Handbuch, Zürich 2002, p. 579 et seq.; Richard Senti, Abkommen über den Handel mit landwirtschaftlichen Erzeugnissen, in: Thürer/Weber/Portmann/Kellerhals (eds.), Bilaterale Verträge I & II Schweiz – EU. Ein Handbuch, Zürich 2007, p. 731 et seq.; Jaag (FN 90), 421.

[93] See Klemm/Trüten (FN 82), p. 154 et seq.; Streinz, Europäisierung (FN 82), p. 201 et seq.

[94] See Streinz, Europäisierung (FN 82), p. 202; Klemm/Trüten (FN 82), p. 155 et seq.

[95] Agreement between the Swiss Confederation and the European Community on the amendment of the Agreement between the Swiss Confederation and the European Economic Community of 22 July 1972 as regards the provisions applicable to processed agricultural products of 26 October 2004 (SR 0.632.401.23). Thereto Richard Senti, Abkommen über landwirtschaftliche Verarbeitungserzeugnisse, in: Thürer/Weber/Portmann/Kellerhals (eds.), Bilaterale Verträge I & II Schweiz – EU. Ein Handbuch, Zürich 2007, p. 789 et seq.; Jaag (FN 90), p. 421 et seq.

[96] See Streinz, Europäisierung (FN 82), p. 203.

Statutory Law

Foodstuffs Act and the Cassis-de-Dijon-Principle

Foodstuffs are generally subject to the FSA. It remains to be examined whether this holds true for foodstuffs that are or contain genetically modified organisms. First follows a short overview of the FSA.

The FSA contains eight chapters. The first chapter sets the aim, the scope and the definitions. The second contains the material provisions. Chapters 3 to 6 contain regulations about the enforcement in a wider sense. Chapter 7 contains criminal law provisions and rights of appeal and chapter 8 the final provisions. The aim of the FSA is to protect consumers from foodstuffs and utility articles that may present a risk to their health, to ensure that foodstuffs are handled hygienically and to protect consumers from deception relating to foodstuffs (article 1 lit. a – c FSA). The scope of application is wide: the manufacture, processing, storage, transport and offering of foodstuffs and utility articles, the labelling and advertising of foodstuffs and utility articles and the import, transit and export of foodstuffs and utility articles (article 2 para. 1 lit. a – c FSA). The FSA also applies to agricultural production to the extent that it is for the manufacture of foodstuffs (article 2 para. 2 FSA). The same provisions apply to imported foodstuffs, provided this is not contradictory to international agreements (article 2 para. 3 FSA). According to article 3 FSA, foodstuffs are defined as nutritional products and luxury foods. Nutritional products are products that are intended to develop and maintain the human body and which are not marketed as therapeutic products. Luxury foods are alcoholic beverages, tobacco and other smoking products. Ingredients are foodstuffs that are added to other foodstuffs or that are used to make up other foodstuffs, as well as additives (article 3 para. 1–4 FSA). Article 4 FSA defines components, additives, foreign substances and article 5 FSA defines utility articles. The distinction between foodstuffs and therapeutic products can prove difficult.[97]

Food may only be used or placed on the market if it meets certain requirements. According to article 6 para. 1 FSA, foodstuffs, additives and utility articles that do not meet the requirements of this Act and its implementation provisions, and in particular those that exceed limit and tolerance values, may not be used or offered to consumers except under certain conditions. As article 1 FSA suggests, these requirements are the protection of health and the protection against fraud. Both objectives are rudimentarily implemented in the law (articles 10, 13 et seq., 15 et seq., 18 et seq., 20 et seq.); the source products are included (article 7 FSA).[98] Additional implementations can be found in departmental ordinances and ordinances adopted by the Federal Council. To ensure that only compliant food products

[97] See Klemm/Trüten (FN 82), p. 140, 142; Tomas Poledna, Inverkehrbringung von Lebensmitteln und Lebensmittelkontrolle, in: Poledna/Arter/Gattiker (FN 82), p. 50 et seq.; see also Judgement of the Federal Court 2A.565/2000 of 8 May 2001 considerations 4a et seq.

[98] See Poledna, (FN 97), p. 52 et seq.

reach the consumers, anyone handling food[99] has a responsibility to ensure compliance (article 23 FSA).[100] Approvals are set aside by the legislator as exceptions. Such an exception is inter alia article 9 lit. b FSA for food derived from genetic engineering methods. Self-control is constrained by a list of approved foodstuff (article 8 para. 1 FSA) and with partial prohibitions and requirements (e.g. traceability [article 23a FSA]).[101] The federal government and the cantons shall enforce the Foodstuff Act (article 32-43a, 24–31 FSA). Based on the FSA, the Federal Council and the Federal Department of Home Affairs (FDHA) have adopted several ordinances.[102]

On 12th June 2009, the Parliament supplemented the Federal Law on Technical Barriers to Trade of 6th October 1995[103] with the Cassis de Dijon principle. According to this amendment, products that are permitted to be marketed in the EU or EEA or in its member States are also permitted to be marketed in Switzerland (art. 16a para. 1 THG). However, special regulations apply to foodstuffs (article 16c lit. f THG). The Cassis de Dijon principle does not apply if products in Switzerland are subject to authorisation (article 16a para. 2 THG). This is the case with genetically modified food, as we shall see below.

Gene Technology Act

The purpose of the GTA is to protect human beings, animals and the environment from abuses of gene technology and to serve the welfare of human beings, animals and the environment in the application of gene technology (article 1 para. 1 GTA). In particular, it shall protect the health and safety of human beings, animals and the environment, permanently conserve biological diversity and the fertility of the soil, ensure respect for the dignity of living beings, enable freedom of choice for consumers, prevent product fraud, promote public information and take account of the significance of scientific research on gene technology for human beings, animals and the environment (article 1 para. 2 lit. a – g GTA). The precautionary and polluter-pays principles are regulated in article 2 GTA, according to which early precautions must be taken to prevent hazards or harm that may be caused by genetically modified organisms. Furthermore, any person who causes measures to be taken under the provisions of this Act shall bear the costs.

Whether foodstuffs fall under the regulation of the GTA depends on the one hand on the scope of application (article 3 GTA), and on the other hand on the definition of genetically modified organism (article 5 GTA). According to article 5 para. 1 and 2 GTA, the term “organisms” denotes cellular or non-cellular biological entities

[99] See Article 2 para. 1 FSA.

[100] See Beatrice Wagner Pfeifer, Grundzüge des Lebensmittelrechts, in: Poledna/Arter/Gattiker (FN 82), p. 21 et seq., p. 23 et seq.; Poledna (FN 97), p. 41 et seq., 46 et seq., 50 et seq.

[101] See in detail Poledna (FN 97), p. 54 et seq.

[102] Read more below.

[103] THG; SR 946.51.

capable of replication or of transferring genetic material. Mixtures, articles and products that contain such entities are also regarded as organisms. An organism is considered as genetically modified when genetic material has been altered in a way that does not occur under natural conditions by crossing or by natural recombination.[104] As such, foodstuffs can be genetically modified organisms or mixtures, articles and products that contain such entities. The GTA applies to the handling of genetically modified animals, plants and other organisms, as well as their metabolic products and wastes (article 3 para. 1). For products obtained from genetically modified organisms, only the regulations on labelling and provisions on public information (articles 17 and 18) apply (article 3 para. 2). Article 3 GTA thus distinguishes between products that are or contain genetically modified organisms (para. 1), and products that are derived from genetically modified organisms (para. 2). For example, while the GTA applies comprehensively with regard to genetically modified tomato or yogurt with genetically modified microorganisms, it only applies partially with to canola oil, which has been produced from genetically modified oilseed rape. In the latter case, only the regulations of the GTA on labelling and provision of public information apply while, for the rest the FSA is applicable in its entirety.

Foodstuffs are therefore subject to both the FSA and the GTA. Article 4 GTA[105] governs the relationship between the GTA and other federal laws concerning the protection of human beings, animals and the environment from hazards or harm caused by genetically modified organisms. "Further" provisions in other federal laws are reserved. "Further" (in German: *weitergehend*) means stricter, as can be concluded from the French (*plus sevère*) and the Italian wording (*più severe*) of the law.[106] Only stricter but not equally strict regulations are reserved. Stricter regulations are considered to be those that protect humans, animals or the environment better from hazards or harm caused by genetically modified organisms and which surpass the GTA with respect to the protection of human health, animals or the environment.[107] Regulations are considered to be stricter not only when they are materially more stringent, but also when they are formally more rigorous.[108] A comparison of the rules of the FSA and the GTA shows that the regulations of the FSA are not stricter than those of the GTA.[109] For the marketing of foods that are or

[104] Cf. Errass, Elemente (FN 49), p. 114 et seq., 116 et seq.; Errass (FN 1), p. 136 et seq.

[105] Article 4 GTA reproduces Article 3 para. 1 EPA (Stricter provisions of other Federal laws shall not be prejudiced), which is not surprising since the GTA emerged from the EPA (see Errass [FN 1], p. 33 et seq., 113 et seq.; Errass, Elemente [FN 49], p. 123).

[106] Cf. Kommission für Wissenschaft, Bildung und Kultur des Ständerates: Bericht vom 30. April 2001, in: AB S 2001, Beilagen Sommersession (= Parliamentarian Committee of Senate for Science, Education and Culture: Report of 30 April 2001, in: AB S 2001, Annexes summer session), p. 22, 23; Errass (FN 1), p. 120.

[107] See Errass (FN 1), p. 120; as well Hansjörg Seiler, Kommentar zum Umweltschutzgesetz (ed. by Vereinigung für Umweltrecht and Helen Keller), 2nd edition, 7th delivery, Zürich 2003, Article 3 N 25.

[108] See Errass (FN 1), p. 120.

[109] See Errass (FN 1), p. 126 et seq., 255. Nothing is changed by the inclusion of the precautionary principle in the FSA (see Message on the Federal Law on Foodstuffs and Utility Articles of 25 May

contain genetically modified organisms, therefore, only the material and procedural requirements of the Gene Technology Act apply.[110] This has several consequences. The authorisation procedure and the material requirements are determined only by the GTA (articles 6, 7 and 12, 13, 14 GTA), as well as the information to recipients (article 15), the product flow segregation (article 16), the labelling (article 17 GTA), the involvement of the Swiss Expert Committee for Biosafety (article 22 GTA) and the Federal Ethics Committee on Non-Human Biotechnology (article 23 GTA). Article 37 para. 2 FSA, according to which the Federal Council may entrust the enactment of provisions of a mainly technical or administrative nature to the federal offices concerned, is in contrast not applicable.

Articles 6 to 9 GTA regulate the material requirements for the material handling with genetically modified organisms, while articles 10 to 14 GTA regulate the procedural requirements. Article 6 GTA describes the protection of human beings, animals, environment and biological diversity. It requires a procedure which follows a step-by-step principle: genetically modified organisms shall only be gradually introduced into the environment; the risks need to be evaluated on each step from a closed system to field trials and finally to the open market. Specifically, article 6 GTA states the following: genetically modified organisms may be released for experimental purposes if the information sought cannot be obtained through experiments in contained systems, if the experiment also contributes to research on the biosafety of genetically modified organisms, if they do not contain genes inserted by gene technology which cause resistance to antibiotics used in human or veterinary medicine and if according to the current state of knowledge, the dispersal of these organisms and their new traits can be excluded and the principles of paragraph 1 cannot otherwise be contravened (article 6 para. 2 lit. a-d GTA).[111] Finally, genetically modified organisms lawfully intended for use in the environment may only be put into circulation if they do not contain gene technologically inserted resistance genes to antibiotics used in human or veterinary medicine, and if experiments in contained systems and field trials have shown that they do not endanger or harm human beings, animals, environment and biological diversity (Article 6 para. 3 GTA).[112] According to article 7 GTA, genetically modified organisms may be handled only in such a way that they, their metabolic products or wastes do not impair production that does not involve genetically modified organisms, or limit consumers' freedom of choice.[113] Article 8 et seq. GTA regulates the respect for the dignity

2011 (Botschaft LMG 2011), in: BBl 2011 5571, 5612 und 5670 [Art. 22 E-LMS]), since the FSA is not more stringent than the GTA.

[110] See Errass (FN 1), p. 127. It seems that experts on foodstuffs law are not aware of Article 4 GTA (e.g. Rolf H. Weber, Bedeutung und Regelungsgegenstände des Lebensmittelrechts, in: Weber/Klemm/Baumgartner/Uebe/Trüten [FN 82], p. 19 et seq., p. 35 et seq.; Klemm/Trüten (FN 82), p. 139, 140 et seq.; Poledna [FN 97], p. 42, 48).

[111] See Errass (FN 1), p. 170 et seq.

[112] See Errass (FN 1), p. 171 et seq., p. 176 et seq.

[113] See Errass, Elemente (FN 49), passim.

of living beings.[114] In principle, the genetic modification of vertebrates is forbidden. Exceptions are allowed only for medical purposes (article 9 GTA).[115] With regard to plants, a weighing of benefits is required between the species-specific properties, functions or habits and the human interests listed in article 8 para. 2 GTA.[116]

The previously mentioned step-by-step principle is reflected in the scheme of procedural requirements: activities in contained systems (article 10 GTA), experimental releases (article 11 GTA) and putting into circulation (article 12 GTA).[117] It should be noted that, in general, each of these steps must be run for each product which is eventually released in the market. However, for certain products such as foodstuffs no field trials are required. The decisive factor is whether they are intended for lawful use in the environment. Before an agricultural product is finally brought to the market as a food, two complete step-by-step procedures (activities in contained systems, experimental releases, putting into circulation) are to be performed: on the one hand with regard to the putting into circulation of plant propagation material (check also agricultural requirements), on the other hand with regard to the putting in circulation as food. For each step, an authorisation procedure is generally[118] provided (article 10–12 GTA). Decisions in these processes are adopted in a coordinated procedure (article 21 GTA) with all involved parties. The act is enforced by the Confederation (article 20 GTA). ECNH[119] and FCBS[120] are to be included into the authorisation process.[121] Articles 15 et seq GTA include special provisions (e.g. product flow segregation, labelling, access to files and public information). According to article 28 GTA, national environmental protection organisations have a right of appeal against authorisations for marketing genetically modified organisms intended for lawful use in the environment, provided that the organisations were set up at least 10 years before the appeal is filed. Articles 30 et seq GTA regulate liability.

The GTA is implemented through several ordinances, of which the following are relevant to the present topic: Foodstuffs and Utility Articles Ordinance of 23rd November 2005,[122] Seeds Ordinance of 7th December 1998[123] and Release Ordinance.

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[114] See Errass, Würde (FN 36), passim.

[115] See Errass (FN 1), p. 155.

[116] See Errass (FN 1), p. 146 et seq.; Errass, Würde (FN 36), p. 219 et seq.

[117] In detail: Errass (FN 1), p. 141 et seq., 243; Errass, Elemente (FN 49), p. 117; Epiney/Waldmann/Oeschger/Heuck (FN 39), p. 112, 186 FN 732.

[118] Exceptions: Article 14 GTA (see Errass (FN 1), p. 193 et seq.

[119] On ECNH see http://www.ekah.admin.ch/en/index.html; Errass (FN 1), p. 201 et seq.; Errass, Würde (FN 36), p. 192 et seq. FN 27.

[120] On FCBS see Errass (FN 1), p. 196 et seq.

[121] Both committees have, in addition, the mandate to advise on legislation (Article 22 para. 2 and Article 23 para. 3 lit. a GTA respectively).

[122] FUO; SR 817.02.

[123] SR 916.151.

To sum up, foodstuffs with genetically modified organism are generally regulated in the GTA and its provisions are implemented in several ordinances. There exists no definition of food safety.

Authorisation of Foodstuffs

Preliminary Remarks

The production of food often requires agricultural raw products.[124] These must meet certain legal requirements for genetically modified organisms, which also indirectly influence the authorisation for food products. Whether these requirements are met, is to be examined within the context of various procedures for approval of *agricultural* production means. A maximum of restrictions exists at this stage. Similar to the release of genetically modified organisms, for agricultural raw products, the step-by-step principle is applicable (activities in contained systems, experimental releases and putting into circulation [articles 6 and 10–12 GTA]). In addition, the requirements of the Agriculture Act are to be considered.

Prohibitions

On the legislative level, article 37a GTA continues the above mentioned and meanwhile expired moratorium, which had been enshrined in the constitution (article 197 Section 7 FC).[125] According to Article 37a phrase 1 GTA, no authorisation may be granted until 31st December 2017 for putting into circulation genetically modified plants and parts of plants, genetically modified seeds and other plant propagation material and genetically modified animals for agricultural, horticultural or silvicultural purposes. Activities in contained systems and experimental field releases are permitted; research should not be impeded. With the concepts of genetically modified plants and parts of plants and genetically modified seeds, reference is made to the definition of article 2 of the Seed Ordinance.[126] To market seed that is contaminated with non-authorised genetically modified organisms is thus unlawful[127] under article 14a of the Seeds Ordinance, even if the seed is intended for the production of these genetically modified foods and the organisms are approved as food (article 14 para. 3 lit. a Seeds Ordinance).

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[124] See also for foodstuffs without genetically modified organism art. 7 FSA.

[125] See Errass (FN 1), p. 84 et seq.

[126] See Message on Extension (FN 74), 5448.

[127] See Christoph Errass, Honig mit gentechnisch veränderten Pollen: Ein Urteil des EuGH und die Folgen für die Schweiz, Jusletter 17. Oktober 2011, Rz. 10 FN 46; see also Errass, Elemente (FN 49), p. 171.

Article 37a GTA also excludes the marketing of genetically modified animals for agricultural, horticultural or silvicultural purposes. Article 9 GTA fundamentally prohibits the production or putting into circulation of genetically modified *vertebrates*.[128] Accordingly, article 37a GTA is limited to only a few animals, such as shellfish or honey bees.[129] Therefore, genetically modified foodstuffs derived from agricultural production – e.g. apples or corn – are not allowed to be produced in Switzerland, but have to be imported, provided an authorisation for the putting into circulation of this genetically modified food exists. After expiry of the moratorium period, an authorisation must be obtained for the marketing of genetically modified seeds (article 12 GTA). However, it must first be examined whether the modification of the genetic material by gene technology violates the dignity of living beings with regard to plants (article 8 GTA); subsequent research is to be carried out in contained systems and in experimental field trials (articles 10 and 11 GTA).[130]

Due to the various current moratoria, Switzerland is a GMO-free zone – apart from the aforementioned unlawful contamination under article 14a Seeds Ordinance. With the expiry of the moratorium, however, the question will arise whether to create a "GMO- free zone" or a zone specifically for the use of genetically modified organisms.[131] It is urgent to answer this question particularly as article 7 GTA protects the production without genetically modified organisms and the freedom of choice. According to article 7 GTA, genetically modified organisms may be handled only in such a way that they, their metabolic products or wastes do not impair production that does not involve genetically modified organisms, or limit consumers' freedom of choice.[132] This article intends not only to ensure a neighbourly field to field coexistence (e.g. field A with genetically modified maize next to a field B with conventional maize), but also to guarantee that in each production phase and after each production process, products can be offered on the market which have been produced without genetically modified organisms. The objective of protection is the production process. The beginning of the production process is especially important, otherwise it cannot be ensured that GMO-free products will not eventually disappear from the market through creeping contamination by genetically modified organisms. This process must not be affected. The departure point must be a principle of "zero" pollution. Otherwise an unacceptable tolerance of contamination would be assumed. In other words, measures must be taken so that threshold values

[128] **Article 9 GTA** Genetic modification of vertebrates

Genetically modified vertebrates may only be produced and put into circulation for purposes of research, therapy, or diagnostics in human or veterinary medicine.

[129] See Message on Extension (FN 74), 5449.

[130] See Errass (FN 1), p. 260 et seq.

[131] See ECNH, Opinion of 19 February 2013 (in German): Koexistenzregelung: Änderung des Bundesgesetzes über die Gentechnik im Ausserhumanbereich, GTG (Vernehmlassungsentwurf vom 30. Januar 2013) und Verordnung über Koexistenzmassnahmen beim Anbau von gentechnisch veränderten Pflanzen sowie beim Umgang mit daraus gewonnenem Erntegut, Koexistenzverordnung, KoexV (Vernehmlassungsentwurf vom 15. Januar 2013), p. 7 et seq.

[132] Comprehensively cf. Errass, Elemente (FN 49), passim; Schweizer/Wildhaber/Rechsteiner (FN 25), passim.

are not exceeded and to prevent that such contamination occurs. If a contamination occurs despite the measures taken, the issue becomes where to draw the line. This should at least be regulated by decree of the Federal Council. To achieve "zero" pollution, many measures are necessary.[133] For example,[134] a clear definition of how to define a GMO-free area,[135] which would be constitutionally permissible,[136] or the definition of areas adjacent to which no genetically modified organisms may be cultivated.[137] From a legal point of view both options can be considered feasible. However, the second option seems to be better in line with Swiss topography, in which GMO-free zones are presumably larger than those, in which GMO could be cultivated. This option also seems to correspond better to the current interests of the farmers.[138] However both options would require the creation of buffer zones.[139]

Authorisation of Genetically Modified Organisms in Food Production

Foodstuffs with genetically modified organisms require an authorisation for being put into circulation (article 12 GTA) – the last step of the step-by-step-principle.[140] For food crops (e.g. apples), this represents the only step, notwithstanding the fact the seeds of the apple tree had already been subject to the relevant permits and conditions set in the law (activities in contained systems, experimental releases and putting into circulation [articles 10–12 GTA]).[141] For other foods such as yogurt with genetically modified organisms, the food regulation requires an authorisation for the handling in closed systems in the first place. In our context, however, the authorisation for putting into circulation is of primary interest.

In order to put into circulation foodstuffs with genetically modified organisms, material (articles 6–9 GTA) as well as procedural requirements (article 12 GTA) must be fulfilled. Foodstuffs with genetically modified organisms may only be

[133] See Errass, Elemente (FN 49), p. 161 et seq.; Schweizer/Wildhaber/Rechsteiner (FN 25), passim.

[134] According to Schweizer/Rechsteiner, in: Schweizer/Wildhaber/Rechsteiner (FN 25), p. 259, the only possible coexistence measure for the production of GM free honey and GM free seeds and seedlings.

[135] Cf. Schweizer/Rechsteiner, in: Schweizer/Wildhaber/Rechsteiner (FN 25), p. 257 et seq.; Epiney/Waldmann/Oeschger/Heuck (FN 39), passim; Errass, Honig (FN 127), Rz. 11.

[136] See Epiney/Waldmann/Oeschger/Heuck (FN 39), p. 73 et seq. (Fazit), p. 108 et seq.; implicitly also Schweizer/Rechsteiner, in: Schweizer/Wildhaber/Rechsteiner (FN 25), p. 257 et seq.

[137] Similar regulations exist for so called quarantine organisms (see Plant Protection Ordinance of 28 February 2001 [SR 916.20]).

[138] See Errass, Honig (FN 127), Rz. 10 f.

[139] See Errass, Honig (FN 127), Rz. 11; Schweizer/Rechsteiner, in: Schweizer/Wildhaber/Rechsteiner (FN 25), 258 Rz. 133.

[140] See Errass (FN 1), p. 243.

[141] See in text above at FN 130.

handled in such a way that they cannot endanger human beings, animals or the environment and do not harm biological diversity or the sustainable use thereof (article 6 para. 1 lit. a und b GTA).[142] In this respect, environmental requirements are to be met in addition to health requirements. The Federal Council has specified these requirements in three substantive ordinances and coordinated the procedures: the RO regulates both the environmental requirements (including an authorisation process) and the process coordination; the FUO regulates health protection (including an authorisation process). These requirements are further detailed in the OGMF.[143]

According to article 22 para. 1 FUO and articles 25 und 26 RO, any person who intends to market foodstuffs, additives and processing aids, which are genetically modified organisms or containing such entities, either for the first time or for a new use shall require an authorisation from the Federal Food Safety and Veterinary Office (FSVO). This is done through a coordinated procedure (see Article 21 GTA; Articles 42 and seq RO; Article 22 para. 3 FUO) involving other federal offices. The applicable procedure (Article 26 RO) depends on the FUO[144] and the OGMF; although additional formal requirements of the RO are to be considered.[145]

The authorisation application for placing genetically modified organisms on the market must be submitted to the FSVO (Article 3 para. 1 OGMF; Articles 25 und 26 lit. b RO). The content of the application depends on the requirements of Annex 1 of the OGMF (e.g. disclosures about the characteristics of the donor and recipient organisms, information on the GMO, information relating to the characteristics and detection of the vector used) and of Article 28 RO (e.g. a technical dossier with the information in accordance with Annexes IIIA or IIIB and IV of the Directive 2001/18/EC,[146] a risk determination and assessment in accordance with Annex 4, an evaluation of interests in accordance with Article 8 GTA that shows that the genetic modification of the genetic material of animals or plants has not failed to respect the dignity of living beings). The authorisation application must show, that in putting the material into circulation neither humans, animals, the environment, biological diversity, the production without genetically modified organisms nor the dignity of living beings are violated (article 28 para. 1 RO). After receipt of the application, the federal offices concerned are to be involved in the evaluation process as well as the two advisory committees: the Federal Biosafety Committee (FBSC) and the Federal Ethics Committee on Non-Human Biotechnology (ECNH) (Article 43 RO, Article 22 para. 3 FUO).[147] The offices check from the perspective of the decrees,

[142] See e contrario Article 14 para. 1 i.f. GTA.

[143] Ordinance of the FDHA about genetically modified foodstuffs of 23 November 2005 (SR 817.022.51).

[144] See Article 26 RO.

[145] To the former law, whose content is still valid nevertheless see Errass (FN 1), p. 251.

[146] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 200144 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (ABl. L 106 of 17.4.2001, p. 1).

[147] Article 4 OGMF is wrong: Each Federal authority examines independently the requirements according to the decrees it is responsible for (see Article 44 para. 1 lit. d RO; Article 22 para. 3

for the execution of which they are responsible, whether the putting into circulation of foodstuffs is permitted. The FBSC examines the application with regard to biosafety (article 22 para. 2 GTA). Their expertise is to evaluate the facts, not to evaluate the acceptability of the safety of a particular use.[148] The ECNH has the task to review the applications from a perspective of ethics and legal ethics (article 23 para. 2 and 3 GTA), and thus to analyze the law or its application from a normative point of view for lack of legally internal or legally external assessment.[149] Since the legal ethical assessment is effected from a position transcending the existing legal system, the committee's opinions may be limited to a specific case but are at any rate to be considered with regard to future legislation.[150]

After the examination, the relevant offices inform the FSVO whether the putting into circulation of foodstuffs is permissible from the perspective of the decrees for whose execution they are responsible. The principle of consent (Article 44 RO, Article 22 para. 3, last sentence FUO) applies. No balancing of interests between conflicting interests is required (e.g. environmental interests on the one hand, health interests on the other). Foodstuffs with genetically modified organisms may be put into circulation only if the requirements of all applicable ordinances have been complied with and provided that all offices have agreed. In addition to the FSVO, the Federal Office for the Environment (FOEN) must examine in each case whether the environment is affected by the genetically modified foods. If need be, the Federal Office for Agriculture (FOAG) is to be integrated into the process (see article 22 para. 3 FUO ["optionally"]; Article 43 para. 1 RO ["in their field of responsibility"]). The authorisation may contain a stipulation or conditions and is to be restricted to ten years (article 5 para. 3 OGMF). The supervision of the market for foodstuffs follows the FSA and the FUO (Article 47 para. 1 lit. b RO). The supervision lies in the responsibility of the cantons (Article 24 et seq, 39 et seq FSA; 56 et seq FUO).

The licensing authority shall authorise marketing, if the assessment of the application leads to the conclusion, that according to the state of the science a health hazard through food can be excluded (Article 22 para. 2 lit. a FUO; Article 5 para. 1 OGMF; Article 44 para. 1 lit. a RO), marketing cannot endanger human beings, animals and the environment or impair biological diversity and the sustainable use thereof (Article 44 para. 1 lit. b RO; Article 22 para. 2 lit. b and c FUO), production that does not use genetically modified organisms and consumers' freedom of choice are not impaired, the assessment of the application, in particular based on the evaluation of interests in accordance with Article 8 GTA, leads to the conclusion that the genetic modification has not failed to respect the dignity of living beings in the animals or plants used (Art. 44 Abs. 1 lit c Ziff. 1 und 2 RO; Art. 7 und 8 GTA) and

FUO). Each authority has its own expertise and evaluates the application accordingly. The FSVO is not competent to provide a wholesale evaluation as little as other Federal Offices are not competent to assess the FSVO's evaluation (cf. Errass [FN 1], p. 256).

[148] See Errass (FN 1), p. 198.

[149] See Errass (FN 1), p. 201 et seq.

[150] Errass (FN 1), p. 204 et seq.

marketing is permissible under the laws enforced by the FSVO and FOEN, and if applicable the FOAG, and these offices therefore approve marketing (Art. 44 Abs. 1 lit. d RO). Whether foods with genetically modified organisms jeopardize or interfere with the various legal goods (health, environment, dignity of living beings, protection of the production without genetically modified organisms and freedom of choice) must be examined in each individual case. It is often the case that the necessary knowledge for the assessment is only being developed during the process of authorisation.[151] The option to appeal is only available to the applicant. Third parties[152] or NGOs[153] are excluded from the possibility to appeal. Appeal bodies are the Federal Administrative Court and the Federal Supreme Court.

The protection of production without genetically modified organisms and freedom of choice (the production does not use genetically modified organisms and consumers' freedom of choice is not impaired) is ensured in the food regulation by the requirements of product flow segregation[154] (Article 16 GTA; Article 25 FUO; Article 10 OGMF) in conjunction with the requirements of labelling[155] and documentation (Article 24 FUO; Article 10 OGMF). In other words, a coexistence regulation between foods with genetically modified organisms and such without is to be guaranteed.[156] Anyone who handles food with genetically modified organisms, and therefore must comply with Article 10 OGMF (product flow segregation), must have an appropriate quality assurance system, which must include in particular the following: the identification of points along the flow of goods when dealing with food, food additives or processing aids, where undesirable mixing may occur, the definition and implementation of measures to prevent this, periodic review of the

[151] See Christoph Errass, Zur Notwendigkeit der Einführung einer Popularbeschwerde im Verwaltungsrecht, AJP 2010, p. 1351 et seq., 1364; Christoph Errass, Recht als Risiko für die Sicherheit oder Sicherheit als Risiko für das Recht, Sicherheit & Recht 2010, p. 24 et seq., 29 with further references, p. 31 et seq. with additional references on gene technology; Burkard Wollenschläger, Wissensgenerierung im Verfahren, Tübingen 2009, passim.

[152] See BGE 123 II 376, pp. 380 f. E. 4b/bb i.f.; discerning Errass, Popularbeschwerde (FN 151), p. 1356 in conjunction with p. 1361 et seq. and in particular 1364; see also Isabelle Häner, Die Beteiligten im Verwaltungsverfahren und Verwaltungsprozess, Zürich 2000, Rz. 726, 748.

[153] See Article 28 GTA: National environmental protection organisations only have a right of appeal against authorisations for putting into circulation of GMO, if genetically modified are intended for use in the environment. This does not include the handling of therapeutic GM products, foodstuffs and animal feedstuffs (Article 3 para. 1 lit. j RO).

[154] See Nikolaus Wenk/Daniela Stebler/Regula Bickel (Europäisches Zentrum für Wirtschaftsforschung und Strategieberatung prognos, Warenflusstrennung von GVO in Lebensmittel, Untersuchung im Auftrag des BAG, Endbericht, Basel 2001).

[155] See below ch. IV.

[156] When passing regulations on product flow segregation and on measures to prevent contamination, the Federal Council shall take account of international recommendations and foreign trade relations (Article 16 para. 2 sentence 2 GTA). It has thereby followed closely the following (two) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed and the Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (see Errass [FN 1], p. 258).

system for its suitability, proper training of persons entrusted with the implementation of these measures as well as documentation of the different specifications and measures. Documentation also helps to achieve the coexistence in food products (Article 24 FUO; Article 8 OGMF). The person who dispenses food with genetically modified organisms then has to inform the recipients by documentation.[157]

Documentation requirements may be waived if no ingredient contains such material (GMOs) in the amount of more than 0.9 % by weight and if it can be proven that all appropriate measures have been taken to prevent the presence of GMOs (Article 24 FUO). In this context, recipients does not refer to consumers but the upstream dealers. If the food in question contains genetically modified organisms, consumers will be informed by labelling. To this we shall return later. A license pursuant to article 6 GTA can be *waived* under article 14 para. 1 GTA if, according to the current state of knowledge or experience, a violation of the principles of articles 6 to 9 GTA (health, environment, animals, biodiversity, protection of production without genetically modified organisms and freedom of choice, dignity of living beings) can be excluded. In this case, the Federal Council may on a general abstract level decide that the use of a particular organism excludes a violation of the principles mentioned.[158] Since no impairment either for the human health or the environment may result from genetically modified organisms an exception in the RO and the FUO is required. The Federal Council has provided such an exception for food.[159] Under article 27 RO, no license is required for marketing foodstuffs, provided that all requirements of article 23 FUO are fulfilled. This article provides inter alia that genetically modified organisms may be tolerated without authorisation if they are present in only small amounts, if it can be shown that the appropriate measures have been taken to avoid their presence, and if, according to the state of science and experience, a violation of the principles referred to in articles 6 to 9 GTG can be excluded. The FDHA specifies the details; the FSVO is responsible for the assessment and the publishing of the list of authorized genetically modified organisms. Details can be found in article 6a OGMF entitled tolerance. According to this article, tolerance applies only to parts that are, contain or are obtained from genetically modified plants. Other genetically modified organisms, especially microorganisms, are not tolerated. In addition, it is required that these parts have been assessed by a foreign authority in a procedure comparable with that of OGMF, that they are suitable for use in food, and that the amount of 0.5 % of the weight, based on the ingredient, is not exceeded. Article 6 para. 1 lit. b para. 3 and para. 2 OGMF emphasize that these parts may jeopardize neither the health nor the

[157] He must indicate that it is or contains GMO; in addition, the GMO has to be named, which has been recognized by unique identifier according to the Commission regulation (EC) No 65/2004 of 14th January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (ABl. L 10 of 16th January 2004 pp. 5 ff.) (Article 8 para. 1 and 2 OGMF).

[158] See Errass (FN 1), p. 193.

[159] See also Wildhaber, Ungewollte Auskreuzungen und die Schwellenwerts-Debatte im Gentechnikrecht, AJP 2009, p. 849 ff., 857.

environment. However, this list is incomplete and unlawful. According to article 14 para. 1 GTA, the principles of articles 6 to 9 shall not be infringed. Therefore, also the tolerance of parts shall impair neither the protection of production without genetically modified organisms nor the dignity of living beings. In this respect, appropriate assessment would be required. In addition, also the procedure regulated in article 6 para. 3 OGMF is incomplete and has to be adjusted to the requirements of GTA (e.g. the consent principle). The tolerable genetically modified organisms are listed in Annex 2 of the OGMF[160]: maize NK603, MON -ØØ6Ø3-6; GA21 maize, MON-ØØØ21-9; 1507 maize, DAS-Ø15Ø7-1.

The production of GM food authorised for marketing (e.g. yoghurt containing microorganisms) usually takes place in contained systems[161]; a license or a notification is required depending on the classification of the organism (article 10 GTA). This is necessary since the authorised organisms only are approved for use in food. The authorisation does not include their handling in the environment.

Labelling

Article 17 GTA regulates labelling. The instrument of labelling must be distinguished from "informing the recipients" of article 15 GTA. Accordingly, any person putting genetically modified organisms into circulation must inform the recipient of the properties that are significant for the implementation of articles 6 to 9 and instruct the recipient in such a way that the principles of articles 6 to 9 are not violated if the organisms are handled appropriately.[162] In other words, subject of these provisions is the appropriate handling of genetically modified organisms. Article 17 GTA, in contrast, intends to ensure freedom of choice for the consumer under article 7 and to prevent product fraud (article 17 para. 1 GTA). In this respect, it is also a provision concerning the protection of human beings, animals and the environment from hazards or harm caused by genetically modified organisms (article 4 GTA), which is relevant for the relationship between the labelling requirements of the GTA and other federal laws.[163]

According to article 17 para. 1 GTA, any person putting genetically modified organisms into circulation must label them as such for the benefit of the recipient, in order to ensure freedom of choice for the consumer under article 7 and to prevent product fraud. The labelling must contain the words "genetically modified"; the Federal Council determines the details. Only the organisms that are brought into circulation must be identified. This includes firstly all organisms which are approved in a regular authorisation procedure under article 12 GTA. Secondly, it includes all

[160] See http://www.blv.admin.ch/themen/04678/04817/04833/04841/index.html?lang=de

[161] Exception: when agricultural crops may be placed on the market directly (i.e. without processing).

[162] See Errass (FN 1), p. 282 et seq.

[163] See Errass (FN 1), p. 286 und above.

organisms which based on article 14 para. 1 GTA may be brought on the market without authorisation, including food, if it meets the requirements of articles 27 RO and 23 FUO.[164]

According to article 5 para. 1 GTA, mixtures, articles and products containing genetically modified organisms are also regarded as genetically modified organisms.[165] As such, they must also be labelled according to article 17 para. 1 GTA. Experience shows, however, that contamination with genetically modified organisms cannot be completely excluded. Based on this, the legislator has granted the Federal Council the competence to lay down threshold values below which labelling is not required for mixtures, articles and products that unintentionally contain traces of genetically modified organisms (article 17 para. 2 GTA, in derogation of article 17 para. 1 GTA). Such traces must be traces of approved genetically modified organisms.[166] Article 17 para. 3 GTA defines when traces are considered unintentional. Traces of genetically modified organisms are considered to be unintentional if the person responsible for providing labelling proves that the product flows have been carefully monitored and recorded.[167] Particularly, the measures under article 7 GTA and the goods flow separation under article 16 GTA serve to achieve this objective. With regard to foodstuffs, the above mentioned measures of documentation and goods low separation apply (articles 24 and 25 FUO; articles 8–10 OGMF). In addition, the Federal Council regulates the labelling of products, in particular of foodstuffs and additives obtained from genetically modified organisms (article 17 para. 4 GTA) and how organisms that are not genetically modified may be labelled as such when they are put into circulation. It also enacts regulations concerning the protection from any misuse of such labelling (article 17 para. 5 GTA). In doing so, the Federal Council takes international recommendations and foreign trade relations into account (article 17 para. 6 GTA).

The FDHA has implemented the requirements for food in article 7 OGMF in more detail. Firstly, it determines the wording in which the labelling must be effected (article 7 para. 1–3 OGMF): "produced from genetically modified X" (for food and additives that are products of GMO[168]) or "made with genetically modified X" (for microorganisms in food).[169] Secondly, it specifies where the reference is to be placed (article 7 para. 4–6). Article 7 para. 7 OGMF then defines the threshold and under what conditions labelling can be waived. The reference may be waived when no ingredient of material that consists of, contains or is produced from GMO exceeds the amount of 0.9 % by mass (excluding micro-organisms referred to in

[164] See text above after footnote 158.

[165] This would be the case even if the contamination were in parts per thousand.

[166] See Errass (FN 1), p. 287 et seq.

[167] See Errass (FN 1), P. 288.

[168] GMO products are food, food additives, or processing aids that are or contain genetically modified organisms, are derived from GMOs or from crossings of different GMOs or are GMO hybrids (see Article 2 OGMF).

[169] Examples can be found on: http://www.blv.admin.ch/themen/04678/04817/04833/04837/index.html?lang=de

para. 3) and when can be proven that appropriate measures have been taken to avoid the presence of such material in the ingredient (article 7 para. 7[bis] OGMF). Article 7 para. 8 OGMF sets out the criteria for negative labelling. For organic products the use of genetically modified organisms is not permitted under article 3 lit. c of the Organic Farming Ordinance[170]; therefore, organic food may not be negatively labelled. With regard to the threshold value, the same rules apply as for the regular products.[171] The labelling requirements generally correspond to the fair trading legislation.[172]

Compliance with the labelling requirements and the rules on goods flow separation are backed with penalties. According to article 35 para. 1 lit. f-i GTA, any person who wilfully violates provisions on product flow segregation and on the precautions to prevent contamination (article 16), puts genetically modified organisms into circulation without labelling them as such for the recipient (article 17 para. 1), violates the provisions on the labelling of products obtained from genetically modified organisms (article 17 para. 4), or puts genetically modified organisms into circulation and labels them as "not genetically modified" (article 17 para. 5) is liable to a custodial sentence not exceeding three years or to a monetary penalty. If the offender acts through negligence, he or she is liable to a monetary penalty not exceeding 180 daily penalty units (article 35 para. 2 GTA). Compliance with the labelling requirements as such are set by national (i.e. cantonal) decrees (cf. article 40 FSA; article 56 et seq FUO).

Liability

Articles 30 et seq GTA contain their own rules on liability with regard to dealing with genetically modified organisms. The general rules on liability in tort or those from the product liability law only apply in a subsidiary manner.[173] The provisions of the GTA were intended to provide a liability regime for damages, which are caused by the application of a new and controversial technology.[174] The most heated debates between opponents and supporters of GMO concern the liability rules,[175]

[170] Ordinance on organic farming and the labelling of organic products and foods of 22 September 1997 (SR 910.18).

[171] See Judgement of the Federal Court 2A.357/2002 of 13 February 2003, considerations 3 and 4.

[172] Cf. Daniel Dédeyan, Macht durch Zeichen, Rechtsprobleme der Kennzeichnung und Zertifikation, Baden-Baden/Zürich/Basel/Genf, 2004, P. 150.

[173] On possibly competing claims see e.g. Christian Hediger, Die Haftungsbestimmungen des Gentechnikgesetzes (Art. 30–34 GTG). Beurteilung und Vergleich mit der Haftungsregelung des deutschen Gentechnikgesetzes, Zürich 2009, p. 128 et seq., 153, 176 et seq.

[174] On the functions of liability: Brülhart (FN 33), p. 108 et seq.

[175] See Errass (FN 1), p. 35 et seq., 38.

which explains why these rules are incoherent and ill-conceived.[176] Article 30 GTA – the main provision – reads:

Art. 30 Principles

1. Any person subject to the authorisation or notification requirement who handles genetically modified organisms in contained systems, releases such organisms for experimental purposes or puts them into circulation without permission is liable for any loss or damage that occurs during this handling that is due to the genetic modification.
2. The person subject to the authorisation requirement is solely liable for any loss or damage that occurs to agricultural or forestry enterprises or to consumers of products of these enterprises through the permitted putting into circulation of genetically modified organisms that is a result of the modification of genetic material if the organisms:
   a. are contained in agricultural or forestry inputs; or
   b. stem from such inputs.
3. In relation to liability under paragraph 2, recourse against persons who have handled such organisms inappropriately or have otherwise contributed to the occurrence or exacerbation of the loss or damage is reserved.
4. If any loss or damage is caused by any other permitted putting into circulation of genetically modified organisms as a result of the modification of the genetic material, the person subject to the authorisation requirement is liable if the organisms are defective. He or she is also liable for a defect which, according to the state of knowledge and technology at the time when the organism was put into circulation, could not have been recognised.
5. Genetically modified organisms are defective if they do not provide the safety that is to be expected taking all circumstances into account; in particular:
   a. the way in which they are presented to the public;
   b. the use that can reasonably be expected;
   c. the time at which they were put into circulation.
6. A product made from genetically modified organisms is not considered defective for the sole reason that an improved product has later been put into circulation.
7. The loss or damage must have been caused as a result of:
   a. the new properties of the organisms;
   b. the reproduction or modification of the organisms; or
   c. the transmission of the modified genetic material of the organisms.

[176] See inter alia Monika Gattiker, Haftung im Umgang mit Lebensmittel, in: Poledna/Arter/Gattiker (FN 82), p. 71 et seq., 78; Christian Hediger, Gentechnikschäden: Hilft das Gentechnikgesetz dem Geschädigten?, HAVE 2009, p. 229 et seq.; Hediger, Haftungsbestimmung (FN 173), p. 78 et seq.; Walter Fellmann, Bauernprivilegien im Haftpflichtrecht – ein Anschlag auf die Schadensprävention!, in: Schmid/Seiler (eds.), Recht des ländlichen Raums – Festgabe für Paul Richli zum 60. Geburtstag, Zürich 2006, p. 129 et seq.; Markus Schott, Gentechnologie in Landwirtschaft und Lebensmittelproduktion nach Inkrafttreten des neuen Gentechnikgesetzes, ZSR 2004 II, p. 435 et seq., 459; see also Alain Griffel/Heribert Rausch, Kommentar zum Umweltschutzgesetz, Ergänzungsband zur 2. Aufl., Zürich 2011, p. 877 et seq., in particular p. 896 et seq. on parallel provisions concerning but the pathogenic organisms of Article 59a^{bis} EPA.

8. A person is exempt from liability if he or she can prove that the loss or damage was caused by an Act of God or through gross misconduct by the injured party or a third party.
9. Articles 42–47 and 49–53 of the Swiss Code of Obligations apply.
10. The Confederation, cantons and communes are also liable in accordance with paragraphs 1–9.

The provisions on liability for genetically modified organisms differ fundamentally between two scenarios. The first scenario is related to damages incurred prior to the putting into circulation and the second scenario concerns damages that occur after the approved putting into circulation. Damages incurred prior to the putting into circulation are regulated in article 30 para. 1 GTA, whilst damages that occur after the putting into circulation are regulated in article 30 para. 2 to 6 GTA. For both scenarios, the loss or damage must have been caused as a result of the new properties of the organisms, the reproduction or modification of the organisms or the transmission of the modified genetic material of the organisms (article 30 para. 7 GTA). This paragraph implements the passages "due to the genetic modification" in article 30 para. 1 and "is a result of the modification of genetic material" in para. 2 and 3 GTA.[177] The proof of a causal connection and of the facts is governed by article 33 GTA, which incorporates the latest case-law.[178] According to this case-law, it is the responsibility of the person claiming damages to prove a causal connection. If this proof cannot be provided with certainty or if production of proof cannot be expected of the claimant, the court may satisfy itself on the balance of probabilities. The court may also have the facts determined ex officio (article 33 para. 1 and 2 GTA). The causality can be interrupted (article 30 para. 8 GTA)[179]: a person is exempt from liability if he or she can prove that the loss or damage was caused by an act of God or through gross misconduct by the injured party or a third party.[180] Damage liability in the legal sense is any involuntary reduction in assets, consisting in a reduction of assets, an increase of liabilities or loss of profit (i.e. financial loss).[181] It is divided into bodily injury (financial loss e.g. as a result of injury) and property damage (financial loss e.g. as a result of damage to property).[182] The GTA accepts this classification and also regulates specifically the environmental damage in article 31 GTA[183]: the person who is liable for handling genetically modified organisms must also reimburse the costs of necessary and appropriate measures that are taken to repair destroyed or damaged environmental components, or to replace

[177] See Hediger, Haftungsbestimmung (FN 173), p. 106 et seq.

[178] See Hediger, Haftungsbestimmung (FN 173), p. 112 et seq.

[179] Given the risks immanent to genetic engineering the legislator could have been stricter (cf. Hediger, Haftungsbestimmung [FN 173], p. 124 et seq.).

[180] Cf Hediger, Haftungsbestimmung (FN 173), p. 123 et seq.

[181] See instead of all Hediger, Haftungsbestimmung (FN 173), P. 94 with further references.

[182] See instead of all Hediger, Haftungsbestimmung (FN 173), p. 94 et seq., 98 et seq., 100 et seq.

[183] See also Felix Schöbi, Der Umgang des Gesetzgebers mit Umweltschäden, URP 2009, p. 463 et seq.

them with components of equal value (para. 1). If the destroyed or damaged environmental components are not the object of a right *in rem* or if the eligible person does not take the measures that the situation calls for, the damages are awarded to the community responsible (para. 2).[184] Whether the pure economic loss is encompassed by the concept of damage with the GTA is debated.[185] In addition, the GTA expanded the periods of limitation (article 32 GTA) from 1 and 10 years to 3 and 30 years respectively.[186] The right to claim damages expires after 3 years from the time when the injured party becomes aware of the loss or damage and of the person liable, but at the latest after 30 years from the time that the event that caused the loss or damage occurred in the company or installation, or ended or the date on which the genetically modified organisms were put into circulation (para. 1). The right to recourse is also limited in accordance with paragraph 1. The 3-year term begins as soon as damages have been paid in full and the person who shares liability is known (para. 2).

The tightened product liability under article 30 para. 4–6 GTA is of pivotal importance for the handling of food.[187] The liable subject must pay compensation only if the organisms are defective, i.e. if the damage occurred as "a result of the modification of genetic material". Genetically modified organisms are defective if they do not provide the safety that is to be expected taking all circumstances into account; in particular the way in which they are presented to the public, the use that can reasonably be expected or the time at which they were put into circulation (article 30 para. 5 lit. a-c GTA).[188] A product made from genetically modified organisms is not considered defective for the sole reason that an improved product has later been put into circulation (article 30 para. 6 GTA). He or she is also liable for a defect which, according to the state of knowledge and technology at the time when the organism was put into circulation, could not have been recognised. The person who holds the approval to put organisms into circulation, i.e. the first person to obtain an authorisation for placing a particular product with specific properties in a specific composition for a particular purpose on the market, is liable for any loss or damage that occurs during this handling that is due to the genetic modification.[189] All following subjects (e.g. retailers) are not liable.[190] The GTA provides exemptions from the licensing requirement, as emphasised earlier. In this case, no one is liable and the

[184] See Hediger, Haftungsbestimmung (FN 173), p. 183 et seq.; Griffel/Rausch (FN 176), p. 891 et seq. on parallel provisions for pathogenic organisms (Art. 59a^{bis} Abs. 9 EPA).

[185] See Hediger, Haftungsbestimmung (FN 173), p. 102 et seq.

[186] See Hediger, Haftungsbestimmung (FN 173), p. 188 et seq.

[187] See Markus Müller-Chen, Haftung für durch gentechnisch veränderte Organismen verursachte Schäden nach Art. 30 ff. Gentechnikgesetz, in: Sutter-Somm et. al. (Hrsg.), Risiko und Recht – Festgabe zum Schweizerischen Juristentag 2004, Basel/Bern 2004, p. 151 et seq., 160; Hediger, Haftungsbestimmung (FN 173), p. 132 et seq. in conjunction with 159; see also Griffel/Rausch (FN 176), p. 888 on parallel provisions on pathogenic organisms (Article 59a^{bis} para. 4 EPA).

[188] In more detail Hediger, Haftungsbestimmung (FN 173), p. 161 et seq.

[189] Thereto Errass (FN 1), p. 244.

[190] See also Hediger, Haftungsbestimmung (FN 173), p. 168; wrong: Gattiker (FN 176), p. 79 et seq.

victims have no one to turn to for redress.[191] In such a case it could be argued that the exemptions can be considered as a general abstract authorisation. Since the exemptions always concern a certain product with specific properties in a particular composition for a specific purpose, it can always be assigned to a producer, i.e. the first person to place the product on the market. In addition, the genetically modified organisms used can be recognised by the identifier.[192]

Article 30 para. 1 GTA applies to the *production* of genetically modified food, which must take place in a closed system, if damage is due to the genetic modification. The person subject to the authorisation or notification requirement is liable for any loss or damage that occurs during this handling that is due to the genetic modification.[193] The facility owner may also be liable under article 59a EPA,[194] which includes environmental damage.[195] Given the poorly elaborated liability provisions of the GTA[196] one should have listened to Lord Denning: "Someone must be trusted; let it be the Judges."[197]

Acknowledgment I would like to thank Ariane Willemsen, lic. iur., M.A. (Philosophy; Guelph/CA) for the discussion, the critical review of the draft and the translation, and Eleanor McGregor, dr en droit, avocate, for the critical review of the translation.

[191] Additional problems see Hediger, Haftungsbestimmung (FN 173), p. 158 et seq. in conjunction with p. 81 et seq.

[192] Cf. e.g. Annex 2 OGMF.

[193] To the different problems with the regulation see Hediger, Haftungsbestimmung (FN 173), p. 81 et seq.

[194] Thereto Hans Rudolf Trüeb, in: Keller/Vereinigung für Umweltrecht (Hrsg.), Kommentar zum Umweltschutzgesetz, 2. Aufl. Zürich 2004, passim ad Art. 59a; Griffel/Rausch (FN 176), p. 867 et seq.

[195] Griffel/Rausch (FN 176), p. 869 et seq.; see also Schöbi (FN 183), p. 477 et seq.

[196] Hediger, Gentechnikschäden (FN 176), passim, and comprehensively Griffel/Rausch (FN 176), p. 897 et seq.

[197] Quoted according to Griffel/Rausch (FN 176), p. 897 Rz. 43 i.f.

Part III
National Reports – America

Chapter 9
Genetic Technology and Food Security: A View from the United States

Margaret Rosso Grossman

Introduction

For decades, plant breeders have developed new plant varieties by mutation or introduction of "uncharacterized genes" into the same species or sometimes between species.[1] Genetic modification (also called genetic engineering), in contrast, "introduces one or a few well-characterized genes into a plant species and … can introduce genes from any species into a plant."[2] Genetic engineering helps to "speed up a naturally occurring biochemical mechanism to more quickly and precisely breed new characters into plants and animals," albeit sometimes in ways "unlikely to occur in nature."[3] The technology has produced crops (e.g., *Bt* [*bacillus thuringiensis*] corn and *Bt* cotton) that resist insects, tolerate herbicides (e.g., glyphosate), and resist viruses (e.g., papaya ringspot virus).

Although genetic engineering is controversial, a number of scientific reports have concluded that these varieties cause no "adverse health or environmental effects" and that "the processes of genetic engineering and conventional breeding

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[1] Pamela Ronald, Plant Genetics, Sustainable Agriculture and Global Food Security, 188 Genetics 11, 12 (May 2011).

[2] Id. at 12. On biotechnology, see generally ISAAA, Agricultural Biotechnology (A Lot More than Just GM Crops) (2014), http://www.isaaa.org.

[3] Gary Marchant et al., Impact of the Precautionary Principle on Feeding Current and Future Generations, at 11 (Issue Paper No. 52, CAST, Ames, Iowa, 2013).

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are no different in terms of unintended consequences to human health and the environment."[4] New crops may enhance nutrition, tolerate environmental stress (e.g., drought), and resist plant diseases. Indeed, three scientists whose work led to development and commercialization of genetically engineered crops received the 2013 World Food Prize, which recognizes people who improve the quality, quantity, or availability of food in the world.[5]

GMOs, Hunger, and Food Security

Cultivation and Acceptance of GM Crops and Food

Cultivation

Genetically modified crops are "the fastest adopted crop technology in the history of modern agriculture."[6] Since 1996, international production increased from 1.7 million hectares to 181.5 million hectares in 2014. The global value of GM seed is about $15.7 billion, and the estimated "global farm-gate revenues of the harvested commercial 'end product' … are more than ten times greater than" the seed value.[7] Leading countries, with GM production on more than 10 million hectares, were the US, Brazil, Argentina, Canada, and India. Twenty-eight countries grew GM crops, and 19 produced at least 50,000 ha. In the European Union, where producers planted 143,000 ha of *Bt* corn, Spain produced 131,500 of those hectares (31.6 % of Spanish maize).[8]

US producers planted 73.1 million hectares (an increase of 4 % from 2013) of GM crops, primarily maize, soybeans, and cotton, in 2014. Indeed, the US

[4] Ronald, supra note 1, at 12. For a list of 610 scientific papers that evaluate the safety of GM food and feed, see http://chilebio.cl/documentos/Publicaciones.pdf (June 2013). A European organization recently indicated that "the potential benefits of crop genetic improvement technologies are very significant," and recommended improvements in EU policy to capture those benefits. European Academies Science Advisory Council (EASAC), Planting the Future: Opportunities and Challenges for Using Crop Genetic Improvement Technologies for Sustainable Agriculture, at 2 (2013).

[5] Andrew Pollack, Executive at Monsanto Wins Global Food Honor, NY Times, 19 June 2013.

[6] Gurdev S. Khush, Genetically modified crops: the fastest adopted crop technology in the history of modern agriculture, 1(14) Ag. & Food Security 1, 2 (2012) (noting a "moral imperative to make GM technology available for public good" and an "urgent need for appropriate science-based, cost-effective and time-effective regulatory systems that are responsible and rigorous but not onerous for small and poor developing countries").

[7] Clive James, ISAAA Brief 49, Global Status of Commercial Biotech/GM Crops: 2014, Executive Summary (2015), http://www.isaaa.org/resources/publications/briefs/49/executivesummary/pdf/B49-ExecSum-English.pdf.

[8] Id., Table 1 (listing production by country). EU production in 2014 was 3 % lower than in 2013.

Department of Agriculture estimated that in 2014, GM varieties were 93 % of corn, 94 % of soy, and 96 % of cotton.[9] In addition, US farmers planted GM canola, sugar beets, alfalfa, papaya, and squash.[10] US regulators have approved 171 GM "events" (not including crops with "stacked" events), more than any country except Japan.[11]

In 2014, for the third consecutive year, farmers in 20 developing countries grew the majority (53 %) of GM crops. Most were "risk-averse small, poor farmers."[12] Producers in China (7.1 million) and India (7.7 million) produced over 15 million hectares of *Bt* cotton. Three African countries grew GM crops in 2014: South Africa (2.7 million hectares), Sudan, and Burkina Faso. Seven conducted field trials,[13] but GM cultivation remains limited in African nations. "Lack of appropriate, science-based and cost/time-effective regulatory systems is the major constraint to adoption. Responsible, rigorous but not onerous, regulation is urgently needed to suit the needs of small farmers and poor developing countries."[14]

Acceptance of GMOs

Farmers

The high percentage of American farmers who cultivate GM corn, soy, and cotton – around 90 %, on average – indicates that these crops have achieved acceptance. Farm income benefits of major GM crops (corn, soy, cotton, and canola) include cheaper and easier weed control, lower production costs, less damage from pests, and sometimes higher yields. US farmers, who were first to adopt GM technology extensively, achieve cost savings and increased production from GM crops; they were the "largest beneficiaries of higher incomes, realizing over $53.2 billion in extra income between 1996 and 2012."[15]

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[9] NASS, USDA, Acreage 25–27 (2014). In 2013, GM varieties made up 90 % of all corn, 93 % of soy, and 90 % of upland cotton. Id.

[10] James, supra note 7; see Table 1.

[11] Id. GM events are approved for release into the environment, cultivation, food, and feed. For a comprehensive overview, see Jorge Fernandez-Cornejo et al., Genetically Engineered Crops in the United States (ERS, USDA, ERR 162, 2014).

[12] James, supra note 7.

[13] Id.

[14] Clive James, ISAAA Brief 49–2014: Top Ten Facts, Fact 7 (ISAAA, 2014).

[15] Graham Brookes & Peter Barfoot, Economic impact of GM crops: The global income and production effects 1996–2012, 5(1) GM Crops & Food: Biotec. Agric. & Food Chain 65, 69 (2014). The authors acknowledge that "[o]ver-reliance on the use of glyphosate and the lack of crop rotation … has [sic] contributed to the development of weed resistance." Id. at 70.

A 2013 survey in the United Kingdom indicated that 61 % of British farmers would grow GM crops, if possible, and 64 % believed GM foods were safe to eat. Survey results: What farmers really think about GM, Farmers Weekly, 12 June 2013, http://www.fwi.co.uk/arable/survey-results-what-farmers-really-think-about-gm.htm.

Despite the benefits of GM technology, acceptance is not uniform. Concern about the possibility of "contamination" of organic, identity-preserved, or traditional crops with GM material raises issues of coexistence. That is, producers want to choose the type of crop they cultivate without fear that pollen drift or admixture of GM and other seeds will affect the purity and marketability of their crop.[16]

Producers who use organic systems are particularly vulnerable to damage from pollen drift or admixture. The US Organic Food Production Act[17] established a certification program for organic production. National Organic Program standards prohibit specific substances, methods (including genetic engineering), and ingredients in organic crop production. Crops labeled as organic may not use GM technology or GM inputs.[18] Livestock products sold or labeled as organic must come from animals raised under organic management with organically produced feed.[19] Unlike organic requirements in the European Union, where food that must be labeled as genetically modified (that is, food with GM content above the 0.9 % threshold) cannot be labeled as organic,[20] US law does not impose a maximum threshold of GM material for foods to be certified and labeled as organic. Therefore, organic certification does not guarantee the absence of GM material, but only that GM inputs were not intentionally used in production.[21] Nonetheless, GM material in organic crops affects marketability.

[16] See Margaret Rosso Grossman, The Coexistence of GM and Other Crops in the European Union, 16 Kan. J.L. & Pub. Pol'y 324 (2007).

[17] 7 U.S.C. §§ 6501–6523; 7 C.F.R. part 205. For current versions of U.S.C. and C.F.R., link from http://www.gpo.gov/fdsys/.

[18] 7 C.F.R. § 205.105. The unintentional presence of a detectable GM residue may not affect organic status, if the operator did not used genetic modification and took reasonable steps to avoid contacts with GMOs.

[19] 7 U.S.C. § 6508; 7 C.F.R. §§ 205.236, 205.237.

[20] Council Regulation 834/2007, arts. 9, 23(3), 2007 O.J. L189, at 1. See Regulations 1829/2003 and 1830/2003, as amended, with thresholds (0.9 %) established in Directive 2001/18, as amended, art. 21(3).

[21] See AMS, USDA, National Organic Program, Final Rule 34 (1990), http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3004452:

> When we are considering drift issues, it is particularly important to remember that organic standards are process based. Certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Act and the regulations. This regulation prohibits the use of excluded methods in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.

Consumers

In comparison with the European Union, where there is little demand for food produced from GM crops,[22] consumers in the United States have expressed less concern about GM crops and their food products. American consumers often display a "dismal level of basic knowledge" about food and agriculture, and they know even less about the prevalence of GM foods in American supermarkets or about the effects of GM ingredients in food.[23] Indeed, a recent study identified significant differences between opinions of scientists and members of the public. Eighty-eight percent of scientists, but only 37 % of other adults, believe that GM foods are safe to eat; moreover, 67 % of adults believe that scientists do not understand the health effects of GM crops.[24]

An October 2013 nationally representative survey indicated that "knowledge and awareness of GM foods are low."[25] Of consumers surveyed, 54 % knew little or nothing about GM foods; 25 % had never heard of GM foods; and only 43 % were aware that GM foods are sold in supermarkets. Some consumers have expressed concerns about GMOs, however, based on moral or religious beliefs (interfering with nature or violating religious dietary restrictions), the desire for freedom of choice (labeling), or GM contamination of traditional or organic crops.[26] Indeed, although many consumers generally accept GM food and others have little knowledge about these foods, an increasing segment of the population demands that GM foods be labeled.[27]

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[22] Michael Cardwell, Public Participation in the Regulation of Genetically Modified Organisms: A Matter of Substance or Form?, 12 Envtl L. Rev. 12, 12–13 (2010). On public protests and vandalism of GM crops in the UK and France, see id. at 25–35. See also David Zilberman et al., Continents divided: Understanding differences between Europe and North America in acceptance of GM crops, 4(3) GM Crops & Food: Biotec. Agric. & Food Chain 202 (2013).

One scholar argued that EU policy on GMOs imposes externalities, including "the negative impact on investment in research and development … [leading to] a reduction in global food security through a reduction in the potential productivity gains which investments in biotechnology can be expected to provide. In other words, a reduction in potential global food supply." William A. Kerr, Food Security and Trade: Some Supply Conundrums for 2050, 15(2) Estey Centre J. Int'l L. & Trade Pol'y 115, 127 (2014).

[23] Alan McHughen, Public Perceptions of Biotechnology, 2 Biotec. J. 1105, 1106 (2007) (quoting survey results indicating that fewer than half of consumers knew that GM foods were in US supermarkets or that eating GM fruit would not alter that person's genes). See also Patrick F. Byrne, Safety and Public Acceptance of Transgenic Products, 46 Crop Sci. 113, 113–114 (2006).

[24] Pew Research Center, Public and Scientists' Views on Science and Society (2015), www.pewresearch.org. Of those with a college education, 49 % believe that GM foods are safe to eat.

[25] William K. Hallman et al., Public Perceptions of Labeling Genetically Modified Foods, at 2–5 (Rutgers School of Environmental and Biological Sciences, 2013).

[26] See, e.g., Dorothy Du, Note, Rethinking Risks: Should Socioeconomic and Ethical Considerations Be Incorporated into the Regulation of Genetically Modified Crops?, 26 Harv. J. L. & Tech. 375, 379–387 (2012). For discussion of the reasons for US opposition, see Brooke Glass-O'Shea, The History and Future of Genetically Modified Crops: Frankenfoods, Superweeds, and the Developing World, 7 J. Food L. & Pol'y 1, 16–22 (2011).

[27] On consumer initiatives, for labeling see infra text accompanying notes 223–226.

Despite lack of knowledge, a 2012 representative survey of US consumers indicated that "[m]ost consumers are favorable toward various benefits offered through plant and animal biotechnology, especially those that have a positive impact on their health and/or the health of the planet. In addition, satisfaction with information currently on food labels and the US Food & Drug Administration's (FDA's) labeling policy for foods produced through biotechnology remains high."[28] A 2014 survey indicated that 28 % of consumers were favorable toward biotechnology; 43 %, neutral; and 29 %, unfavorable.[29] Consumers were most enthused about biotechnology used to reduce pesticide applications, stabilize food prices, and provide food for the world. In fact, almost half (46 %) favored biotechnology intended "to grow more crops that would help meet food demand," and 55 % favored use for food in developing countries.[30] Fewer consumers (31 %) had favorable attitudes toward animal biotechnology, often blaming lack of information. Nonetheless, about 69 % of consumers would buy products of transgenic animals, and 59 % would buy transgenic fish if the FDA approved their safety.[31]

Government

The US government recognized the potential of crop biotechnology in its early regulatory documents (discussed below) and has consistently supported biotechnology. The US recently emphasized the role of biotechnology in global food security by supporting the 2013 Joint Statement on Innovative Agricultural Production Technologies, Particularly Plant Biotechnologies. The statement recognized the

[28] International Food Information Council (IFIC), Consumer Perceptions of Food Technology Survey, Executive Summary, at 3 (2012). In 2012, US consumers expressed concern about biopharming (production of pharmaceuticals and industrial chemicals in crops). On pharming, see generally Eckard Rehbinder et al., Legal problems of pharming, in Pharming, at 213–289 (Springer, Berlin, 2009). Maine, for example, prohibited open-air production of genetically engineered pharmaceutical crops. Maine Rev. Stat. Ann. tit. 7, §§ 1051, 1055.

[29] International Food Information Council (IFIC), Consumer Perceptions of Food Technology Survey (2014) [no page numbers]. Fewer consumers were favorable toward biotech foods than in 2012 (38 %), but more were neutral (26 % in 2012) and unfavorable (20 %). Changes in 2014 may reflect state labeling initiatives and publicity. In 2014, only about 11 % of consumers surveyed had read or heard "a lot" about food biotechnology, and 89 %, only a little or nothing. Thirty-seven percent believed that biotech foods were available in US supermarkets, but with some inaccurate beliefs about what foods.

[30] Id. Consumers were more likely to buy GM foods that offer health benefits (about 70 %), improve taste (58 %), or come from crops that reduced pesticide use (69 %). Scientists in Europe found that consumers would pay a premium for GM foods with health benefits (biofortified crops), but would purchase GM foods with benefits for producers only with a discount. Hans De Steur et al., Status and market potential of transgenic biofortified crops, 33(1) Nature Biotec. 25, 27 (2015).

[31] IFIC, supra note 29. About 29 % of consumers were unfavorable; 25 % were neutral; and 15 % didn't have enough knowledge. Only 7 % of consumers had a lot of information about animal biotechnology; 45 %, a little; and 48 %, none.

global need for increased food production and that "innovative agricultural technologies … play a critical role in … contributing to increased food production in a sustainable way, and in mitigating the adverse effects of climate change."[32] The statement emphasized the importance of transparent science-based regulations, consistent with principles and guidelines of the Codex Alimentarius Commission, synchronization of authorizations for new products, continued research, and other cooperation.[33]

Some have asserted that the US government supports agricultural biotechnology excessively. Food and Water Watch, an NGO that promotes safe, accessible, and sustainable food, argued that the US State Department followed "a concerted strategy to promote agricultural biotechnology, often over the opposition of the public and governments, to the near exclusion of other more sustainable, more appropriate agricultural policy alternatives" for developing countries.[34] The NGO analyzed diplomatic cables and concluded that the State Department worked to "improve the image of biotech crops overseas, coordinate with biotech seed companies and press foreign governments to adopt pro-biotech policies."[35] Food and Water Watch demanded that the State Department stop its "aggressive advocacy of pro-biotech policies in the developing world" and instead encourage "economically and environmentally sustainable farming" and "let the biotech seed industry handle its own public relations."[36]

Food Security

International

The UN Food and Agricultural Organization (FAO), which focuses on international aspects of food security, noted in 2004 that "[f]ood security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life.

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[32] FAS, USDA, Joint Statement (2013), http://www.fas.usda.gov/joint-statement-innovative-agricultural-production-technologies-particularly-plant-biotechnologies. Other supporting governments are Australia, Brazil, Canada, Argentina, and Paraguay.

[33] See Codex Alimentarius, Foods derived from modern biotechnology (2d ed., 2009) (collecting principles and guidelines), ftp://ftp.fao.org/docrep/fao/011/a1554e/a1554e00.pdf.

[34] Food & Water Watch, Biotech Ambassadors: How the U.S. State Department Promotes the Seed Industry's Global Agenda, at 2 (2013).

[35] Id. at 3. Food and Water Watch analyzed 926 cables discussing biotechnology released by Wikileaks in 2010, but did not use secret cables. The NGO identified four goals of biotech diplomacy: to promote business interests of biotech companies, to encourage foreign governments to weaken rules for biotechnology (opposing labeling), to protect biotech exports, and to encourage the developing world to adopt GM crops. Id. at 8, 11.

[36] Id. at 16.

The four pillars of food security are availability, stability of supply, access, and utilization."[37] The FAO's 2009 Declaration on Food Security from the Rome World Summit on Food Security adopted this definition, but added "[t]he nutritional dimension is integral to the concept of food security."[38]

The FAO estimated that about 805 million people (11.3 % of world population), most (791 million) in developing countries, were "chronically undernourished in 2012–2014."[39] In 2009, the FAO's World Food Summit estimated that "agricultural output will have to increase by 70 %" between now and 2050 to feed the world population, which may exceed 9 billion.[40] Moreover, "[c]limate change poses additional severe risks to food security and the agriculture sector. Its expected impact is particularly fraught with danger for smallholder farmers in developing countries … and for already vulnerable populations."[41]

The US Department of Agriculture (USDA) defines and tracks food security both internationally and in the US. For its analysis of lower income countries, the USDA defines food insecurity as a situation in which "per capita food consumption for a country … falls short of the nutritional target of roughly 2,100 calories per capita per day" from grains, root crops, and other dietary components.[42] The nutritional gap reflects the difference between availability of food and the food needed to meet the nutritional target. The distribution gap, which reflects access to food and purchasing power, measures "the food needed to raise consumption … to the nutritional requirement."[43] It indicates the intensity of food insecurity and hunger.

The USDA estimated that in 2014, 490 million people (about 14 % of the population) in 76 lower-income countries were food insecure, with a distribution gap of 12.7 million tons. By 2024, the USDA expected 598 million people (14.6 % of the population) to be food insecure, with a distribution gap of 17.8 million tons (28 % higher than in 2013).[44] Sub-Saharan Africa (39 countries), where hunger is most

[37] FAO, Voluntary Guidelines to support the progressive realization of the right to adequate food in the context of national food security, at 5, para. 15 (27th Session of the FAO Council, Nov. 2004).

[38] World Food Summit, Declaration of the World Summit on Food Security, at 1, n. 1 (FAO, WSFS 2009/2, Rome, 16–18 Nov. 2009), http://www.fao.org/fileadmin/templates/wsfs/Summit/Docs/Final_Declaration/WSFS09_Declaration.pdf.

[39] FAO, IFAD & WFP, The State of Food Insecurity in the World 2014: Strengthening the Enabling Environment for Food Security and Nutrition, at 8–9 (FAO, Rome, 2014) (indicating that with more effort the Millennium Development Goal – to reduce by half the proportion of undernourished – for 2015 may be within reach, but the World Food Summit goal of reducing by half the number of undernourished cannot be achieved).

[40] World Food Summit, supra note 38, at 2, para. 4.

[41] Id. at 2, para. 5.

[42] Stacey Rosen et al., International Food Security Assessment, 2014–2024, at 2 (USDA, GFA-25, 2014).

[43] Id. at 2.

[44] Id. at 1, 3, Table 2a. In 2000, more than 1 billion people, 37 % of the population, were food insecure; the distribution gap was 24 million tons. Birgit Meade & Stacey Rosen, International Food Security Assessment, 2013–2023, at 14 (USDA, GFA-24, 2013), citing World Food Programme statistics.

intense, is expected to have increased food insecurity: 258 million people in 2014; 346 million in 2024.[45]

United States

In 2006, USDA adopted new terms to describe "ranges of severity of food insecurity" in the United States.[46] High food security means no reported problems with food access. Marginal food security involves one or two indications of anxiety about food sufficiency, but without changed diet or food consumption. Low food security is indicated by reduced "quality, variety, or desirability of diet," but with little or no indication of reduced consumption. Very low food security is characterized by "multiple indications of disrupted eating patterns and reduced food intake." Food insecurity, an economic and social condition, is different from hunger, "an individual-level physiological condition that may result from food insecurity" and that is difficult to assess accurately.[47] Moreover, food insecurity is related to food prices. Since 2006, US food prices have increased by almost 20 %, significantly more than the 14 % increase in the consumer price index.[48]

The USDA analyzes data from annual food security surveys conducted by the US Census Bureau. In 2013, 14.3 % of US households (17.5 million) were food insecure, and 5.6 % (6.8 million) had very low food security.[49] Both children and adults in almost 10 % (3.8 million) of households with children under 18 were food insecure in 2013.[50] Food insecurity is associated with income. Among "households with annual incomes below the official poverty line" (in 2013, $23,624 for a family of 4), 42.1 % were insecure, but only 6.7 % of households with incomes over 185 % of poverty line faced food insecurity.[51] Rates of food insecurity were also higher than the national average for households headed by a single parent, households with children, and Black and Hispanic households.[52] Food assistance programs offer

[45] Rosen et al., supra note 42, at 1, 3, Table 1. In 2024, food insecurity in Sub-Saharan Africa is projected to affect 31.2 % of the population. Id. at 5. In West Africa, the ebola virus will increase food insecurity, at least in the short term. See Anne-Claire Thomas et al., European Commission, Impact of the West African Ebola Virus Disease Outbreak on Food Security (Joint Research Centre, Ispra, Italy, 2014).

[46] ERS, USDA, Definitions of Food Security, http://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/definitions-of-food-security.aspx (last updated 3 Sept. 2014).

[47] Id. (all quotations).

[48] Richard Volpe, Price Inflation for Food Outpacing Many Other Spending Categories, Amber Waves (Aug. 2013), link from http://www.ers.usda.gov/amber-waves/2013-august/.

[49] Alisha Coleman-Jensen et al., Household Food Security in the United States in 2013 (ERS, USDA, ERR 173, 2014). Food insecure households "were, at times, unable to acquire adequate food … because they had inadequate money and other resources for food." Id. at 8.

[50] Id. at 8. Nearly 20 % of those households with children were food-insecure. In 9.6 % of those households, parents provided food for their children first, so only adults were food insecure.

[51] Id. at 12.

[52] Id. at 14.

help, and 62 % of households that were food insecure in 2013 participated in a federal food and nutrition program.[53] Despite significant hunger, however, the US remains the most food-secure nation.[54]

Food Aid

The US contributes to global food security by donating significant amounts of food aid to more than 150 countries.[55] Nonetheless, several long-standing food aid practices are inefficient and costly: "[l]imits on the US ability to support local and regional purchase of food aid, the practice of monetization, and costly cargo shipping requirements."[56] Monetization provides US food to NGOs, which sell it to raise cash for development projects. A requirement that food be produced in the US and shipped to needy countries results in high costs; in at least one program, transportation and administration consumed a majority of expenditures.[57] Moreover, some practices have raised controversy. For example, in 2002, when shipments of food aid during famine in Southern Africa included GM corn, Zambia refused GM food, and other countries insisted that corn be milled so that it could not be planted.[58]

The influential Chicago Council on Global Affairs recently recommended that the US adopt a "cash-based food aid system," end monetization, and instead provide cash to NGOs. These policies would maximize US food aid for "alleviating poverty and hunger and, most importantly, saving lives."[59] President Obama, too, recommended reforms.[60] Although these recommendations were not adopted in full, the

[53] Id. at 29. Three major programs are Supplemental Nutrition Assistance Program (SNAP, earlier called food stamps), National School Lunch Program, and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Id. at 27.

[54] Economist Intelligence Unit, Global Food Security Index 2013, at 6 (2013). The US, Norway, and France are the most food secure. Developing countries improved their food security between 2012 and2013.

[55] USAID, The Future of Food Assistance: U.S. Food Aid Reform (Fact Sheet, 2013). See Food for Peace Act, 7 U.S.C. §§ 1691–1738r.

[56] Chicago Council on Global Affairs, Advancing Global Food Security: The Power of Science, Trade, and Business, at 75 (Catherine Bertini & Dan Glickman, co-chairs, 2013). US Food Aid is not part of Feed the Future, discussed below. Id. at 39.

[57] U.S. Gov't Accountability Office (GAO), Foreign Assistance: Various Challenges Impede the Efficiency and Effectiveness of U.S. Food Aid, at 15, 37–38 (GAO-07-560, 2007). See also GAO, International Food Aid: Prepositioning Speeds Delivery of Emergency Aid, but Additional Monitoring of Time Frames and Costs is Needed (GAO-14-277, 2014).

[58] See Noah Zerbe, Feeding the famine? American food aid and the GMO debate in Southern Africa, 29 Food Pol'y 593 (2004) (arguing that US food aid policy was designed to promote adoption of GM crops, rather than to alleviate famine).

[59] Chicago Council, supra note 56, at 75.

[60] USAID, supra note 55. President Obama's 2014 budget proposed reforms to make US food aid programs more flexible and efficient. Although food aid with US commodities would continue when appropriate, aid would also include vouchers, cash, and locally-sourced food for emergencies. The President also proposed to end monetization, making more food aid available. Id.

Agricultural Act of 2014 reauthorized US food aid statutes through 2018 and amended some provisions.[61] The Act included amendments designed to improve nutritional quality of food aid and to prevent disruption of local markets. It also enacted a new local and regional food purchase program.[62]

Food Waste and Loss

Food waste and loss contribute to food insecurity when food feeds landfills instead of hungry people. In 2010, about 133 billion pounds (31 % of food, worth about $161 billion) of wasted food from stores, restaurants, and homes reached US landfills.[63] In June 2013, the USDA and EPA initiated a Food Waste Challenge, intended to "ensure that our nation's food goes to our families and those in need – not the landfill."[64] The Challenge, which involves partner organizations, will "reduce food loss and waste; recover wholesome food for human consumption; and recycle discards to other uses including animal feed, composting, and energy generation."[65]

Food waste is an international problem, with 2009 global food loss from farm to fork estimated at 32 % of food by weight and 24 % of calories. Most waste occurred in the developed world, but 44 % occurred in the developing world, where food insecurity is most prevalent.[66] Reducing global food loss and waste, even by half, would be a significant step toward meeting the needs of the projected world population in 2050.[67] Moreover, food waste has an annual economic impact of $750 billion and

[61] Title III of the Agricultural Act of 2014, Pub. L. 113–79, 128 Stat. 649 (2014), signed into law in February 2014.

[62] Ralph M. Chite, Coordinator, The 2014 Farm Bill: A Comparison of the Conference Agreement with the Senate-Passed (S. 954) and House-Passed (H.R. 2642) Bills, at 9–10 (CRS R43076, 2014).

[63] Jean C. Buzby et al., The Estimated Amount, Value, and Calories of Postharvest Food Losses at the Retail and Consumer Levels in the United States, at 11 (ERS, USDA, EIB 121, 2014). Consumer losses were 21 % and retail losses, 10 % of the food supply. The study did not consider losses earlier in the food chain (e.g., postharvest loss of produce). Not all food loss can be prevented, due to "technical and spatial factors; consumers' tastes, preferences, and food habits; and economic factors." *Id.* at 22.

[64] Press Release, USDA, USDA and EPA Launch U.S. Food Waste Challenge (No. 0112.13, 4 June 2013). In the US, 30–40 % of food is wasted.

[65] USDA, http://www.usda.gov/oce/foodwaste/index.htm# (format changed).

[66] Tim Searchinger et al., Creating a Sustainable Food Future: A Menu of Solutions to Sustainably Feed More Than 9 Billion People by 2050, at 28 (World Resources Institute Report, 2013); Brian Lipinski et al., Reducing Food Loss & Waste, at 5 (World Resources Institute Working Paper, 2013) (relying on FAO data). See also House of Commons, International Development Committee, Global Food Security (HC 176, 2013) (recommending targets to reduce food waste, with sanctions).

[67] Lipinski et al., supra note 66, at 9. Food loss also wastes water and land, increases CO2 emissions, and releases methane in landfills. For strategies to reduce food loss see Searchinger et al., supra note 66, at 28–33.

leaves an environmental footprint, affecting critical natural resources by causing loss of water, land, and biodiversity and contributing to climate change.[68]

Food Security and Biotechnology

Feeding the world's growing population poses challenges. By 2050, a 60–110 % increase in global agricultural production may be necessary to meet demands from "increasing human population, meat and dairy consumption from growing affluence, and biofuel consumption."[69] Researchers noted that a yield increase rate of 2.4 % per year would double production by 2050. But global average yield increases for four critical crops are lower: maize, 1.6 %: rice, 1 %; wheat, 0.9 %; and soybeans, 1.3 %.[70] In many nations, yields are not increasing enough to meet projected food demand, and "sustainable intensification" may be necessary to ensure adequate food.[71] Scientists recommend various approaches to food security, including closing the yield gap (that is, the difference between current and maximum local productivity) sustainably, increasing production limits (using GM and non-GM technologies), changing to more plant-based diets, and expanding aquaculture.[72]

A Role for Biotechnology?

Genetically modified crops may help to satisfy global food demands. Researchers have calculated that GM crops carry significant "positive yield effects." Between 1996 and 2012, additional global production of soybeans was 122.3 million tons; maize, 230.5; cotton, 18.2; canola, 6.6.[73] Farmers in developing countries enjoyed significant net economic benefits (46.6 % of the 2012 total of $18.8 billion) from GM production.[74] GM crops also improve nutrition by offering higher levels of

[68] See generally FAO, Food Wastage Footprint: Impacts on Natural Resources, Summary Report (FAO, Rome, 2013).

[69] Deepak K. Ray et al., Yield Trends Are Insufficient to Double Global Crop Production by 2050, 8(6) PLOS/One 1, 1 (June 2013), http://www.plosone.org.

[70] Id. at 2 (using about 2.5 million statistics from about 13,500 political units, between 1961 and 2008, with focus on the last two decades). Recent research has found evidence of "yield plateaus or abrupt decreases in rate of yield gain" between 1990 and 2010 and suggests that farmers have already achieved maximum yields for some cereal crops. Patricio Grassini et al., Distinguishing between yield advances and yield plateaus in historical crop production trends, 4 Nature Comm., art. 2918, DOI:10.1038/ncomms3918 (2013).

[71] Ray et al., supra note 69, at 6. On sustainable intensification, see T. Garnett et al., Sustainable Intensification in Agriculture: Premises and Policies, 341 Sci. 33 (5 July 2013).

[72] H. Charles J. Godfray et al., Food Security: The Challenge of Feeding 9 Billion People, 327 Sci. 812, 813–17 (12 Feb. 2010).

[73] Brookes & Barfoot, supra note 15, at 72, Table 7.

[74] Id. at 69.

important micronutrients. Indeed, scientists have asserted that "[b]iotech crops could potentially do much to relieve the problem of under-nutrition," and that plant breeders have no other technologies to create improved varieties, "none which can overcome the physiological and environmental limitations of global agriculture to produce sufficient food, feed, fuel, and fiber on the available land to meet increasing demand."[75]

International and US policy statements accept a role for GM crops in achieving food security. For example, the 2009 World Food Summit articulated strategic objectives and principles for achieving food security. Among the principles is an approach that combines action to combat hunger in the short term and programs to eliminate hunger in the medium and long term. Agriculture, including biotechnology, plays a significant role:

> We recognize that increasing agricultural productivity is the main means to meet the increasing demand for food given the constraints on expanding land and water used for food production. We will seek to mobilize the resources needed to increase productivity, *including the review, approval and adoption of biotechnology and other new technologies and innovations that are safe, effective and environmentally sustainable*.[76]

The 2009 World Food Summit endorsed the L'Aquila Food Security Initiative.[77] Under this initiative, the US contributes to global efforts to reduce world hunger, especially in Africa, through USAID's Feed the Future Program.[78] Biotechnology plays a role in this broad government effort. As part of its support of global food security, Feed the Future aims in part to "to strengthen national frameworks for adoption of agricultural biotechnology."[79] Feed the Future's research strategies include "the use of advanced genomics and biotechnology to improve the resilience of crops and animals to climate stresses."[80]

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[75] American Council on Science and Health, Feeding the World with Modern Agricultural Biotechnology, at 20 (2013), http://www.acsh.org. See generally Nina V. Fedoroff & Drew L. Kershen, Agricultural Biotechnology – An Opportunity to Feed a World of Ten Billion, 118(4) Penn State L. Rev. 859 (2014).

[76] World Food Summit, supra note 38, at 5, para. 26 (emphasis added). As the FAO noted in 2013, little additional land is available for agriculture, because potential cropland is forest, environmentally protected, or in urban uses. FAO, FAO Statistical Yearbook 2013: World Food and Agriculture, at 10 (FAO, Rome, 2013). See UN Environment Programme, Assessing Global Land Use: Balancing Consumption with Sustainable Supply (2014) (indicating that a global expansion of cropland to meet food demand in 2050 raises issues of sustainability).

[77] G-8, L'Aquila Joint Statement on Global Food Security (July 2009), http://www.g8.utoronto.ca/summit/2009laquila/2009-food.pdf, expanded by the G-20 in Pittsburgh, Leaders' Statement: The Pittsburgh Summit, para. 39 (Sept. 2009), https://g20.org/wp-content/uploads/2014/12/Pittsburgh_Declaration_0.pdf.

[78] Feed the Future is part of the New Alliance for Food Security and Nutrition, an association of donors, global and African companies, and African governments. Among the global companies are biotech seed and agribusiness companies, including Monsanto, DuPont, Cargill, and Syngenta. Feed the Future, Progress Report: Boosting Harvests, Fighting Poverty, at 28 (2012).

[79] Id. at 6.

[80] Id. at 23. See also Feed the Future, Global Food Security Research Strategy, at 42, 43 (2011). A World Resources Institute report accepts a role for genetic engineering, along with conventional

As the US employs GM technology to aid food insecure nations, some caution is in order. "There are particular issues involving new technologies, both GM and non-GM, that are targeted at helping the least-developed countries. The technologies must be directed at the needs of those communities," and those nations should be involved in "framing, prioritization, risk assessment, and regulation of innovations."[81]

Climate Change

GM crops may prove critical in light of difficult growing conditions in developing countries and the need to adapt to expected changes in global climates.[82] An adequate global food supply may require crops that are more productive and more resilient to changes in climate, including availability of water.[83] Resilience to drought provides an example. In 2010, the US accounted for 53.2 % of world exports of corn; 44.1 % of soy, 27.8 % of wheat, and 41.9 % of cotton.[84] The 2012 drought that affected much of US agricultural land resulted in significant losses of yield and income for corn and soybean producers in the US and increased food prices in the US and worldwide. Moreover, corn and soy exports declined.[85] Because exports of US crops make up a significant portion of world exports, drought in the US affects global availability of food and feed.

Drought tolerant crops are expected to contribute significantly to food security, by helping to increase global productivity. In 2013, Monsanto launched DroughtGard

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breeding in sustainable food production:

> Genetic engineering can play a role, particularly because improved techniques now allow insertion of genes in particular locations, reducing the amount of trial and error necessary to produce crops with improved traits (such as pest or drought resistance). In the short run, genetic engineering can most help by enabling faster breeding responses to new pests. More fundamental crop improvements from genetic engineering, such as improved uptake of nutrients and reduced losses of water, are uncertain and will take decades to come to fruition.
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> Searchinger et al., supra note 66, at 6.

[81] Godfray et al., supra note 72, at 816 (noting, at 815, that GM technology "should neither be privileged nor automatically dismissed"). For the conclusions that GM crops "have a significant role to play in agriculture development in African countries south of the Sahara" and that some crops could benefit African smallholder farmers, see José Falck-Zepeda, Genetically Modified Crops in Africa: Economic and Policy Lessons from Countries South of the Sahara, at 224–225 (IFPRI, Washington DC, 2013).

[82] On the global significance of reducing greenhouse gas emissions while increasing production, see Searchinger et al., supra note 66, at 83–93.

[83] See generally L. Val Giddings et al., Feeding the Planet in a Warming World: Building Resilient Agriculture through Innovation (ITIF, Washington DC & LSE, London, 2013) (asserting, at 21–23, that global regulatory regimes for GMOs stifle innovation).

[84] US Census Bureau, The 2012 Statistical Abstract, National Data Book, at 548, Table 852.

[85] Paul C. Wescott & Michael Jewison, Weather Effects on Expected Corn and Soybean Yields, at 9 (ERS, USDA, FDS-13g-01, 2013). See also ERS, USDA, U.S. Drought 2012: Farm and Food Impacts, http://www.ers.usda.gov/topics/in-the-news/us-drought-2012-farm-and-food-impacts.aspx. Accessed 13 Feb. 2015.

GM corn in the Western Great Plains of the US.[86] Moreover, Monsanto and BASF, which developed the technology, donated it to the Water Efficient Maize for Africa (WEMA) partnership, with plans to make the maize available in Sub-Saharan Africa by 2017.[87] Increased yields are critical because corn is a staple food for 300 million people in Africa, where hunger and malnutrition are common.[88] Other GM drought-tolerant crops are under development, as are crops with tolerance to salinity, heat stress, and cold.[89]

Enhanced Nutrition

The next generation of genetically modified foods is expected to offer nutritional advantages. A new version of Golden Rice fortified with β-carotene (a precursor of Vitamin A) and a nutritionally-fortified banana are in development. Unfortunately, campaigns, including destruction of field trials, by NGOs (e.g., Greenpeace) have delayed introduction of Golden Rice, which can prevent blindness and early death.[90] Virus-resistant cassava and a fungal-resistant banana may enhance availability of staple foods.[91] Indeed, current GM crops may offer health benefits. *Bt* corn has reduced contamination of corn with fumonisin, a mycotoxin that increases the risk of neural tube defects. Research suggests that corn tortillas made with *Bt* corn help to protect the babies of a group of Mexican-American women.[92]

Genetically enhanced feed crops are also expected to contribute to food security, albeit indirectly, by helping to provide "[s]ufficient, nutritious and environment-

[86] Monsanto, Genuity DroughtGard Hybrids, http://www.monsanto.com/products/Pages/drought-gard-hybrids.aspx. US producers planted only 50,000 ha of DroughtGard in 2013 and 275,00 ha in 2014. James, supra note 7.

[87] James, supra note 7. On WEMA, a private/public sector partnership, see http://wema.aatf-africa.org/.

[88] See Gret O. Edmeades, Progress in Achieving and Delivering Drought Tolerance in Maize – An Update (ISAAA, 2013).

[89] ISAAA, Biotechnology and Climate Change, Pocket K No. 43 (2013), link from http://www.isaaa.org/kc. GM crops also help to mitigate climate change by decreasing emission of greenhouse gases (lower pesticide application) and sequestering carbon (no-till farming). Id. at 2.

[90] Bruce Alberts et al., Editorial, Standing Up for GMOs, 341 Sci. 1320 (20 Sept. 2013). See also Editorial, Fight the GM Food Scare: Mandatory labels for genetically modified foods are a bad idea, Sci. Am., Sept. 2013, at 10: "Greenpeace and other anti-GMO organizations have used misinformation and hysteria to delay the introduction of Golden Rice to the Philippines, India and China."

[91] Daniel Cressey, A New Breed, 497 Nature 29 (2 May 2013). Recent research suggests that orange plants engineered with a spinach gene can resist citrus greening, a disease that threatens Florida citrus production. Venessa Wong, Can Genetically Modifying an Orange With a Spinach Gene Save Florida's Crop?, Bloomberg Businessweek, 17 Dec. 2013.

[92] Drew L. Kershen, Health and Food Safety: The Benefits of Bt Corn, 61 Food & Drug L.J. 197, 197–206 (2006) (explaining the science of neural tube defects and the effect of Bt corn on fumonisin concentrations).

friendly feed crops" for animals.[93] Feed grains modified for increased amino acids to improve protein content may help to reduce the need for food supplements and reduce excretion of nitrogen.[94] Trials of feed crops with other enhancements show promise. Feed crops with improved fatty acids, reduced toxins and harmful "anti-nutritive factors," for example, seem to offer nutritional advantages. "Nutritionally-enhanced genetically modified feeds have consistently shown efficacy in providing safe and available nutrients to poultry and livestock in various studies."[95]

The Right to Food

According to the former UN Special Rapporteur on the Right to Food, "[t]he right to food is a human right recognized under international law which protects the right of all human beings to feed themselves in dignity, either by producing their food or by purchasing it."[96] Elements of this right include availability of food, accessibility (both economic and physical), and adequacy to satisfy dietary needs.

International agreements establish the right to food. The 1948 UN Universal Declaration on Human Rights established that "[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food."[97] Parties to the 1966 International Covenant on Economic, Social and Cultural Rights recognized "the right of everyone to an adequate standard of living for himself and his family, including adequate food" and, "recognizing the fundamental right of everyone to be free from hunger," agreed to take measures to improve the production, conservation, and distribution of food.[98] FAO's 1996 World Food Summit

[93] ISAAA, Nutritionally-Enhanced GM Feed Crops, Pocket K No. 41 (2012), link from http://www.isaaa.org/kc. Other advantages may follow. For example, improved phosphorus availability in GM crops with the phytase enzyme can help to reduce excretion of phosphorus and the resulting pollution.

[94] Id. at 1–2. These include corn with increased lysine; rice with elevated free tryptophan, used for chicken feed; soybeans enriched with more digestible amino acids; lupin with increased methionine for broiler chickens.

[95] Id. at 4.

[96] Olivier de Schutter, Right to Food, http://www.srfood.org/en/right-to-food. De Schutter served from 2008 to 2014, and the quotation is no longer at this web address.

[97] UN General Assembly, Universal Declaration on Human Rights, art. 25(1) (Doc. 217 A (III), 10 Dec. 1948), http://www.un.org/en/documents/udhr.

[98] UN General Assembly, International Covenant on Economic, Social and Cultural Rights, art. 11(1),(2) (16 Dec. 1966, in force 3 June 1976), 993 U.N.T.S. 3, 7 (1976). Article 2, id. at 5, sets out the concept of "progressive realisation," requiring parties to take steps to realize the rights recognized in the Covenant. See also UN Economic and Social Council, Committee on Economic, Social and Cultural Rights, General Comment No. 12 (Doc. E/C.12/1999/5, 12 May 1999) (discussing issues concerning art. 11). In August 2013, the Covenant had 160 Parties and 70 Signatories.

pledged to reduce hunger,[99] and the 2000 UN Millennium Declaration committed to "halve, by the year 2015, the proportion of the world's people … who suffer from hunger."[100] In 2004, the FAO adopted Voluntary Guidelines to help states implement the right to food,[101] and a 2012 Fact Sheet outlines state obligations.[102]

The US supports the right to an adequate standard of living, including food, established in the Universal Declaration of Human Rights and is committed to the Millennium Development Goals. The US, however, is not a Party to the 1966 International Covenant.[103] The objective of the US is "to achieve a world where everyone has adequate access to food," but the US does not "treat the right to food as an enforceable obligation"[104] and is one of the few countries that has not acknowledged a right to food. Nonetheless, the US government helps to feed the hungry both in the US and in the world through nutrition assistance programs, food aid, and other measures. Indeed, people in the US who meet eligibility criteria are entitled by law to receive nutrition assistance. Some argue, however, that particularly for the hungry at home, the US must shift its policy focus from "food assistance as charity to adequate food as a human right," to ensure that food is accessible, nutritious, and available.[105]

[99] FAO, Rome Declaration on World Food Security, World Food Summit, Rome, 13–17 Nov. 1996, http://www.fao.org/docrep/003/w3613e/w3613e00.HTM.

[100] UN General Assembly, Millennium Declaration (Doc. A/Res/55/2, 18 Sept. 2000), http://www.un.org/millennium/declaration/ares552e.pdf.

[101] FAO, Voluntary Guidelines, supra note 37 (a "soft-law" document, adopted by consensus).

[102] UN Office of High Commissioner for Human Rights & FAO, The Right to Adequate Food (Fact Sheet No. 34, 2012).

[103] President Jimmy Carter signed the Covenant, 5 Oct. 1977, but the US has not ratified it. See also the Protocol of San Salvador (1988) to the OAS American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (1969), signed but not ratified by the US. Art. 12(1) of the San Salvador Protocol: "Everyone has the right to adequate nutrition which guarantees the possibility of enjoying the highest level of physical, emotional and intellectual development."

[104] US Mission to the UN, Explanation of Position by the United States of America on Resolution: The Right to Food, UN Human Rights Council, 19th Session (Geneva, Switzerland, 22 Mar. 2012) (joining the consensus document, albeit with reservations). See UN General Assembly, Human Rights Council, The Right to Food, in Report of the Human Rights Council on its nineteenth session 22 (Doc. A/HRC/19/2, 24 May 2013), http://www.ohchr.org/EN/HRBodies/HRC/RegularSessions/Session19/Pages/19RegularSession.aspx.

[105] International Human Rights Clinic (IHRC), Nourishing Change: Fulfilling the Right to Food in the United States, at 3 (NYU School of Law, 2013) (describing US programs). Fifteen federal food assistance programs exist. Requirements (e.g., income thresholds) limit eligibility, and Congress must appropriate funds. See also Molly D. Anderson, *Beyond food security to realizing food rights in the US*, 29 J. Rural Stud. 113, 114 (2013).

Authorization of GMOs

Legal Requirements for Authorization of GMOs in Food Production

Under US law, GM crops and their food and feed products must be authorized, after evaluations designed to protect agriculture, the environment, and health.[106] Those who develop new varieties must comply with federal laws and regulations; developers also complete voluntary consultations with federal agencies.[107] The 1986 Coordinated Framework for Regulation of Biotechnology,[108] which established US policy, relied on existing federal law, now supplemented by new laws and regulations. Under the Coordinated Framework, the US Department of Agriculture (USDA) ensures that GMOs are safe to grow; the US Environmental Protection Agency (EPA) ensures that they are safe for the environment; the US Food and Drug Administration (FDA, along with the EPA) ensures that they are safe to eat. Because the focus of this discussion is food, the following description will treat the roles of USDA and EPA briefly, with more focus on the FDA. Moreover, the focus is food from GM plant varieties, rather than food from genetically engineered animals, which the FDA regulates as new animal drugs.[109]

US Department of Agriculture

Under the authority of the Plant Protection Act of 2000,[110] USDA's Animal and Plant Health Inspection Service (APHIS) governs interstate movement, import, field testing, and release of GM plants. The Plant Protection Act authorizes

[106] This section on authorization of GMOs is condensed from Margaret Rosso Grossman, Genetically Modified Crops and their Products in the United States: A Review of the Regulatory System, in José Martinez, ed., XI Jahrbuch des Agrarrechts, at 69–95 (Nomos, Baden-Baden, 2012).

[107] See Phillips McDougall, The Cost and Time Involved in the Discovery, Development and Authorization of a New Plant Biotechnology Derived Trait (Study for CropLife International, 2011). The cost of traits introduced between 2008 and 2012 is $136 million, over an average of 13.1 years from initiation to commercial sale. Registration and regulatory issues consume about 5.5 years.

[108] Office of Science and Technology Policy (OSTP), Coordinated Framework for Regulation of Biotechnology Products, 51 Fed. Reg. 23,302 (26 June 1986) (drafted in cooperation with administrative agencies). See also OSTP, Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753 (27 Feb. 1992) (describing a "risk-based, scientifically sound approach to the oversight," id. at 6753).

[109] FDA, Guidance for Industry 187: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs (2011), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf.

[110] 7 U.S.C. §§ 7701–7772 (replacing the Plant Pest and Plant Quarantine Acts). Section 7711 authorizes regulation of plant pests.

restrictions on plant pests, defined broadly in APHIS regulations,[111] which govern the process of authorization.[112] Because most GMOs are materials that could harbor a plant pest, they are "regulated articles," which must be evaluated and classified as "nonregulated" before they can be sold commercially.[113]

The USDA uses a science-based regulatory framework to ensure safe development and use of GM plants. APHIS regulations require extensive data, and field trials evaluate safety. Trials that pose special risks require permits, and applications require detailed information about the new GMO. To comply with the National Environmental Policy Act (NEPA),[114] APHIS prepares an environmental assessment followed, if necessary, by an environmental impact statement. Permits, if granted after review of the application, may impose conditions; they require the permit holder to report unanticipated incidents and results of field trials to APHIS. For most GMOs without novel plant risks, however, field trials use a less stringent notification process. Regulations prescribe the procedure (including required data) for notifying APHIS and impose performance standards for field trials.[115]

When field trials succeed – that is, if the new variety is not a plant pest and poses no threat to agriculture or the environment – the developer petitions for determination of nonregulated status. APHIS reviews results of field trials and detailed data about the organism; again, the agency must comply with NEPA. If APHIS concludes that the variety can be released safely into the environment and poses no agricultural risk, the agency makes the determination of nonregulated status. Thereafter the nonregulated organism can move freely in commerce, but only if it

[111] 7 C.F.R. § 340.1; 7 U.S.C. § 7702(14).

[112] 7 C.F.R. part 340. In 2008, USDA proposed regulatory amendments to expand its oversight, but by February 2015, these amendments had not been promulgated. APHIS, Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms: Proposed Rule, 73 Fed. Reg. 60,008 (9 Oct. 2008), corrected at 73 Fed. Reg. 66,563 (10 Nov. 2008), to be codified at 7 C.F.R. part 340. Beginning in March 2012, APHIS provided more opportunities for public comment about petitions for nonregulated status. See APHIS, Enhancements to Public Input, link from http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology. For criticism of USDA regulation, see, e.g., Emily Montgomery, *Genetically Modified Plants and Regulatory Loopholes and Weaknesses under the Plant Protection Act*, 37 Vt. L. Rev. 351 (2012).

[113] A regulated article is an "organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent … meets the definition of plant pest." 7 C.F.R. § 340.1.

[114] 42 U.S.C. §§ 4321–4370 f. NEPA requires preparation of an environmental impact statement for "major Federal actions significantly affecting the quality of the human environment." Id. § 4332(2)(C).

APHIS' failure to prepare environmental impact statements has engendered litigation, and a case involving Monsanto's Roundup Ready alfalfa reached the US Supreme Court. Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139, (2010). See Margaret Rosso Grossman, Monsanto Co. v. Geertson Seed Farms: US Supreme Court Decides GM Alfalfa Case, 5(4) Eur. Food & Feed L. Rev. 216–221 (2010).

[115] 7 C.F.R. §§ 340.4 (permits), 340.3 (notifications). USDA proposed to eliminate the notification procedure and require permits for all field trials. APHIS, supra note 112.

also meets EPA and FDA requirements. As of January 2015, APHIS had granted 117 petitions, with 8 applications pending.[116]

Environmental Protection Agency

Plant incorporated protectants (PIPs) in GM crops are pesticidal substances – e.g., *bacillus thuringiensis* (*Bt*), an insecticide – produced by GM crops. The EPA regulates PIPs under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[117] and governs food safety issues of pesticide residues in GM foods under the Food, Drug, and Cosmetic Act (FDCA).[118] Regulations establish requirements under both laws, and a guidance document sets out policy.[119]

The EPA uses the FIFRA registration system to evaluate the safety, efficacy, and environmental effects of PIPs, which are pesticides because they are introduced into plants as a means of "preventing, destroying, repelling, or mitigating any pest."[120] No pesticide can be sold and used in the US until it has been registered. Registration requires, among other things, a showing that the pesticide will not "cause unreasonable adverse effects on the environment."[121] To support registration, the developer gathers data in field tests, authorized by experimental use permits.[122] If a field test could result in a food residue, the EPA can establish a temporary food tolerance under the FDCA before issuing the permit.[123] The EPA may register a new GMO with pesticidal properties when the developer complies with regulatory requirements.[124]

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[116] Statistics on permits, notifications, and petitions, as well as APHIS documents related to applications, are available at APHIS, USDA, Biotechnology, http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml (updated daily). In 2013, the agency approved 602 releases, and in 2014, 534. Information Systems for Biotechnology, Summary data, http://www.isb.vt.edu/release-summary-data.aspx. See also Fernandez-Cornejo et al., supra note 11.

[117] 7 U.S.C. §§ 136–136y.

[118] 21 U.S.C. §§ 301–399d, supplemented by the Food Safety Modernization Act, Pub. L. 111–353, 124 Stat. 3885 (2011), codified at 21 U.S.C. §§ 2201–2252.

[119] 40 C.F.R. parts 152 & 174; EPA, Pesticide Registration (PR) Notice 2007–2: Guidance on Small-Scale Field Testing and Low-Level Presence in Food of Plant-Incorporated Protectants (PIPs) (Docket EPA-HQ-OPP-2007-0654-0001, 2007), http://www.epa.gov/PR_Notices/pr2007-2.htm.

[120] 7 U.S.C. § 136(u). The EPA defines PIP as "a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for [its] production." 40 C.F.R. § 174.3.

[121] 7 U.S.C. § 136a(c)(5). Unreasonable adverse effects are defined at id. § 136(bb).

[122] 7 U.S.C. § 136c; 40 C.F.R. part 172. Some small-scale field tests do not require permits. 40 C.F.R. § 172.3; EPA, Notice 2007–2, *supra* note 119.

[123] 7 U.S.C. § 136c(b). A food tolerance is a legal limit on the maximum amount of a substance in or on a food.

[124] PIPs, which are produced and used in living plants, are different from other pesticides, so PIPs present unique regulatory issues. The EPA planned to promulgate regulations with data requirements designed for PIPs, but those regulations had not been adopted by February 2015. EPA,

The Food, Drug, and Cosmetic Act, which governs residues of PIPs in foods,[125] prohibits adulteration and misbranding and regulates food additives.[126] Raw or processed food or feed that contains pesticide chemical residues is considered adulterated and cannot be moved in interstate commerce unless the residue complies with an established tolerance or has been exempted from the tolerance requirement.[127] The EPA may establish a pesticide tolerance for foods only if it is "safe."[128] The EPA may grant exemptions, either temporary or permanent, from the tolerance requirement if tests indicate that the pesticidal protein is neither toxic nor allergenic, and there is "a reasonable certainty that no harm will result" from aggregate exposure.[129] By regulation, the EPA has granted exemptions to PIPs in GM crops (for example, proteins associated with *Bt* crops).[130] The FDA enforces the EPA's pesticide tolerances.

Food and Drug Administration

The FDA, which governs food and feed safety under the FDCA, articulated its initial policy for GM varieties and their food products in a 1992 Policy Statement.[131] Because most new plant varieties had been developed safely, the FDA did not routinely conduct premarket safety reviews of new foods derived from plants, and its policy extended this approach to GM foods.[132] The FDA acknowledged, however, that genetic modification could cause changes in structure, function, or composition. Therefore, if necessary to protect public health, the agency can require premarket review and approval of new foods.[133] The agency emphasized that developers of new

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Notification, 76 Fed. Reg. 14,358 (16 Mar. 2011) (Docket EPA-HQ-OPP-2009-0499, to amend 40 C.F.R. parts 152, 158, 174).

[125] 21 U.S.C. § 346a.

[126] Until 1996, pesticide residues were considered food additives and subject to the Delaney Clause, 21 U.S.C. § 348(c)(3)(A), that prohibited approval of substances that contain carcinogens. They are now governed separately, *id*. § 346a.

[127] 21 U.S.C. § 346a(a)(1). Scientific data must support requests for tolerances or exemptions. See also EPA, Notice 2007–2, *supra* note 119, at 3, 6–7.

[128] 21 U.S.C. § 346a(b)(2)(A)(i). Safe means "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id*. § 346a(b)(2)(A)(ii).

[129] *Id*. § 346a(c)(2)(A)(i),(ii).

[130] Exemptions are codified 40 C.F.R. §§ 174.501–174.533 (2013).

[131] FDA, Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 23,005 (29 May 1992) (FDA, 1992 Policy). The FDA has authority to regulate substances intended to enhance plant resistance to chemical herbicides (e.g., glyphosate).

[132] *Id*. at 22,988.

[133] *Id.* at 22,986–22,990, citing 21 U.S.C. § 342(a)(1). At the developer's request, the FDA reviewed the Flavr Savr tomato (FDA Docket No 91A-0330) to determine whether it was as safe as other tomatoes and concluded that no significant safety differences existed. See FDA, Calgene, Inc; Availability of Letter Concluding Consultation, 59 Fed. Reg. 26,647 (23 May 1994).

foods bear legal responsibility to evaluate food safety and to comply with the FDCA.[134]

The FDA focuses on the food product, rather than the process: "The regulatory status of a food … is dependent upon objective characteristics of the food and the intended use of the food (or its components) … , rather than the fact that the new methods are used."[135] The agency relied on its existing regulatory system, especially FDCA provisions that prohibit misbranding and govern food additives,[136] to ensure the safety of GM foods and food ingredients.

FDA policy relies in part on the concept of substantial equivalence,[137] "an internationally recognized standard that measures whether a biotech food or crop shares similar health and nutritional characteristics with its conventional counterpart."[138] A GM food product is considered substantially equivalent to its conventional counterpart if their nutritional components do not differ. The FDA requires premarket review only for foods that lack substantial equivalence – foods with characteristics that carry higher risk (e.g., toxin levels or a new substance).[139] In 2001, the agency proposed, but has not yet promulgated, a regulation that would require notice at least 120 days before commercial distribution of most bioengineered foods, so that the FDA could resolve questions of harm to health or misbranding and ensure that GM foods comply with the FDCA.[140] The agency did not plan to require premarket approval for all GM foods.

Food Additives

The FDA's authority to regulate food additives applies to GM food. The FDCA provides that a food is adulterated if it bears or contains an added "poisonous or deleterious substance which may render it injurious to health," an unsafe pesticide

[134] See FDA, 1992 Policy, *supra* note 131, at 22,990.

[135] *Id*. at 22,984–22,985. A National Academy of Sciences report agreed that a "policy to assess products based exclusively on their method of breeding is scientifically unjustified." NAS, Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects, at 9 (NAS, Washington DC, 2004).

[136] 21 U.S.C. §§ 342, 348.

[137] FDA, 1992 Policy, *supra* note 131, at 22,992 (referring to OECD and FAO/WHO documents). Substantial equivalence is a comparative approach, rather than a safety assessment.

[138] Council for Biotechnology Information, Substantial Equivalence in Food Safety Assessment, at 1 (2001). In analyzing gene products, the first step is evaluation for allergenicity, acute toxicities, and major "compositional components." If the protein is safe, the second step focuses on substantial equivalence.

[139] For criticism, see Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 Univ. Mich. J.L. Reform 403, 426–432, 484 (2002).

[140] FDA, Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4711 (18 Jan. 2001). Because consultation is successful and protects public health, the FDA indicated that the rule may not be needed. U.S. Gov't Accountability Office, Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, But Could Take Additional Steps to Enhance Coordination and Monitoring, at 44 (GAO-09-60, 2008).

residue, or an unsafe additive.[141] A food additive is considered unsafe unless it has been granted premarket approval or is exempt from approval.[142] Approval requires the manufacturer to submit data showing, with "reasonable certainty … that the substance is not harmful under the intended conditions of use."[143] If the FDA finds the additive safe, it will approve the additive by regulation; otherwise additives are considered unsafe, and the food is adulterated.[144]

Most non-pesticidal GM foods escape rigorous premarket review as food additives, however, because the FDA applies the GRAS concept to GM foods.[145] Substances that are "generally recognized as safe" (GRAS)[146] – e.g., ingredients from natural sources and some chemical additives – are excluded from the statutory definition of food additive.[147] GRAS substances are therefore exempt from regulation as food additives.[148] The determination that a substance is GRAS, however, requires "the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient."[149]

The FDA decided that most GM foods would be considered GRAS because most new plant foods had been accepted widely as safe.[150] Although a lawsuit challenged

[141] 21 U.S.C. § 342(a) (defining adulterated food). Any substance that is not "an inherent constituent of food or whose level in food has been increased by human intervention" is "added" under 21 U.S.C. § 342(a)(1). FDA, 1992 Policy, *supra* note 131, at 22,989.

[142] 21 U.S.C. § 348(a). The Food Additives Amendment, enacted in 1958, did not address foods from new plant varieties, which had been regulated under § 342(a)(1).

[143] 21 C.F.R. § 170.3(i). See 21 U.S.C. § 348(b),(c) (requirements for petition and approval).

[144] 21 U.S.C. § 342(a)(2)(C). "The term 'safe' … has reference to the health of man or animal." *Id*. § 321(u).

[145] See Fred H. Degnan, The GRAS Concept: Ensuring Food Safety and Fostering Innovation, in FDA's Creative Application of the Law: Not Merely a Collection of Words, at 15–35 (FDLI, Washington DC, 2006). The FDA has applied different interpretations to the GRAS provisions, but GRAS is considered "a tool capable of more flexibility, thus permitting realistic food safety decisions and fostering new technology and innovation." *Id*. at 15.

[146] The regulatory definition of GRAS, 21 C.F.R. § 170.30, reads in part:

> (a) General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. … General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

[147] A food additive is a substance that is "*not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures … to be safe under the conditions of its intended use.*" 21 U.S.C. § 321(s).

[148] FDA, 1992 Policy, supra note 131, at 22,989. The current GRAS list is published in 21 C.F.R. parts 182, 184, 186.

[149] 21 C.F.R. § 170.30(b). See Degnan, supra note 145, at 26–28 (reviewing litigation on the standard for GRAS determination).

[150] FDA, 1992 Policy, supra note 131, at 22,990. The agency did not expect "any serious question about the GRAS status of transferred genetic material," unless the substance (e.g., protein, carbohydrate, fat, oil) differed "significantly in structure, function, or composition from substances found currently in food."

this determination, the court held that the FDA's presumption of GRAS status for GM foods was not arbitrary and capricious. Emphasizing that the GRAS determination must be based on technical evidence of safety, generally known and accepted in the scientific community, the court deferred to the FDA's evaluation of scientific data within its area of expertise.[151]

The characterization of GM foods as GRAS is controversial.[152] Manufacturers themselves decide whether a new food substance is GRAS and not a food additive that requires FDA approval.[153] The FDCA does not require manufacturers to inform FDA about new GRAS substances[154] but uses a notification procedure set out in a 1997 proposed regulation.[155] The agency responds to GRAS notices with a "no questions" letter; response does not constitute approval.[156] In December 2010, the FDA reopened the comment period on its proposed GRAS notification regulation and planned to issue a final rule.[157]

Guidance Documents

FDA guidance documents, used to communicate the agency's current views, are less formal than regulations and do not legally bind the FDA or the public.[158] Nonetheless, the FDA uses guidance documents to structure industry consultations about new GM foods.

In its 1992 Policy Statement, the FDA stated that "prudent" developers of foods using new technologies, including new plant varieties, would consult with FDA (the

[151] Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 177 (D. D.C. 2000), citing 21 C.F.R. § 170.30(a),(b).

[152] See, e.g., Alison Peck, Leveling the Playing Field in GMO Risk Assessment: Importers, Exporters and the Limits of Science, 28 B.U. Int'l L.J. 241, 252–63 (2010).

[153] See Thomas G. Neltner et al., Conflicts of Interest in Approvals of Additives to Food Determined to Be Generally Recognized as Safe, JAMA Internal Med. (7 Aug. 2013), DOI:10.1001/jamainternmed. 2013.10559 (analyzing financial conflicts of interest and questioning the independence of GRAS determinations).

[154] See 21 U.S.C. § 348; McGarity, supra note 139, at 455. See also 21 C.F.R. § 170.35 (voluntary petition for affirmation of GRAS status, to be replaced by notification).

[155] FDA, Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938 (17 Apr. 1997). Any person can notify the FDA of a claim that a particular use of a substance is exempt from premarket approval as GRAS.

[156] See FDA, Guidance for Industry: Frequently Asked Questions about GRAS, Q 15 (2004). Since 1998, FDA received 550 GRAS notices. Although most notifiers received "no questions" letters, some notifiers withdrew GRAS notices, and other notices remain pending. FDA, GRAS Notice Inventory, http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm (last updated 31 Oct. 2014).

[157] FDA, Substances Generally Recognized as Safe; Reopening of the Comment Period, 75 Fed. Reg. 81,536 (28 Dec. 2010); FDA, supra note 155.

[158] Erica Seiguer & John J. Smith, Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances, 60 Food & Drug L.J. 17, 20 (2005).

"biotechnology consultation") before commercial distribution of those foods.[159] The agency's 1997 guidance document on consultation procedures for industry establishes procedures for initial and final consultations.[160] A comprehensive data form facilitates collection of information for the final consultation, which occurs when the developer has documentation – including detailed safety and nutritional assessments – to show that its new product is safe.[161] FDA scientists meet with developers and review data to identify and resolve scientific and regulatory issues. Although biotechnology consultation is voluntary, food companies follow the practice,[162] perhaps in part to avoid possible liability triggered by unsafe foods.

The FDA also recommends that developers seek early food safety evaluation of certain new non-pesticidal proteins in GM food varieties. A 2006 guidance document encourages developers to submit food safety data at the time of field tests, before new proteins enter the food supply via pollen flow or commingling.[163] Early food safety evaluation occurs even before the biotechnology consultation that precedes commercialization, and developers can use data from the food safety evaluation in the later consultation.[164]

Restriction of GMOs

In comparison with the EU,[165] few restrictions limit the cultivation and use of approved GMOs and GM food and feed in the US. Under federal law, producers are free to cultivate GM varieties that have received USDA approval (nonregulated status). Seed manufacturers, however, may impose restrictions on producers by contract – e.g., a requirement to plant a "refuge" area of non GM plants in the area.[166]

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[159] FDA, 1992 Policy, supra note 131, at 22,991.

[160] FDA, Guidance on Consultation Procedures – Food Derived from New Plant Varieties (1997), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096126.htm.

[161] See FDA, Notice, Agency Information Collection Activities, 76 Fed. Reg. 9,020 (16 Feb. 2011). The form is FDA 3665, available on the FDA website.

[162] See FDA, Completed Consultations on Bioengineered Foods (updated 28 Nov. 2014), http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing.

[163] FDA, Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, at parts II, III.C. (2006), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatory Information/Biotechnology/ucm096156.htm. As discussed above, the EPA regulates PIPs.

[164] Id. part III.C.3. See FDA, Inventory of New Protein Consultations (updated 27 Mar. 2013), http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm222595.htm.

[165] For information about European restrictions, see GMO-free Europe, http://www.gmo-free-regions.org/.

[166] To protect intellectual property (a subject beyond the scope of this report), seed developers prohibit saving and replanting seeds. Bowman v. Monsanto Co., 569 U.S. __, 133 S. Ct. 1761 (2013) (without permission of the patent holder, a farmer cannot reproduce patented seeds by planting and harvesting).

Moreover, because the USDA, FDA, and EPA share information and coordinate approvals, GM food varieties approved for cultivation can also be sold or processed as food and feed.[167]

State Restrictions

A number of states have enacted laws that govern GM crops and other products. Although some states regulate GM crops (e.g., by permit), states generally support GM technology. State laws authorize funding for research, create criminal penalties or impose statutory damages for destruction of GM research or field crops, preempt local government prohibitions of GM cultivation, and protect innocent farmers when GM material is found on their land.[168] Like federal law, a few state laws restrict the use of biotechnology in organic production.[169]

Although the FDA has not yet approved genetically engineered animals for food, a few states have enacted restrictions on genetically engineered animals. For example, in 2014, California made it "unlawful to spawn, incubate, or cultivate any transgenic species of … Salmonidae in this state," extending to all state waters a 2003 ban that applied to waters of the Pacific Ocean regulated by California.[170]

In the last decade, some unapproved GM crop varieties (Starlink corn, ProdiGene corn, LL601 rice, and a glyphosate-tolerant wheat) have been discovered in farm fields or in the food chain, resulting in significant harm to producers, seed companies, and trade. In response, a few states enacted laws that govern the production of crops – e.g., rice or canola. These laws apply to both GM and traditional varieties. The California Rice Certification Act of 2000 is designed to avoid harmful commercial impacts caused by commingling of rice varieties.[171] The Act authorizes the California Rice Commission to approve field tests, review rice varieties before planting in California, and to regulate production and handling of rice to avoid commingling.[172] Similarly, the Arkansas Rice Certification Act of 2004 authorizes the

[167] See US HHS, USDA, USEPA, Memorandum of Understanding (Doc. 10-2000-0058-MU, 2011), http://www.epa.gov/opp00001/biopesticides/pips/biotech-mou.pdf.

[168] See Margaret Rosso Grossman, Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort, in Luc Bodiguel & Michael Cardwell, eds., The Regulation of Genetically Modified Organisms: Comparative Approach, at 299, 317–321 (OUP, Oxford, 2010). For a list of state biotechnology laws, see National Conference of State Legislatures, State Biotech Statutes (2011), http://www.ncsl.org/research/agriculture-and-rural-development/state-biotech-statutes.aspx.

[169] E.g., Michigan Organic Products Act of 2000, Mich. Comp. Laws § 286.907(d) (excluding use of GM organisms from definition of organic agriculture). On federal restrictions, see supra text accompanying notes 17–21.

[170] California A.B. 504, Chap. 444, Statutes of 2014, codified in the Cal. Fish & Game Code, chap. 3, div. 3. Researchers could grow GE fish in closed systems (tanks).

[171] Cal. Food & Ag. Code §§ 55000–55123; see § 55009 (characteristics of commercial impact); §§ 55080–55083 (commercial impact rice).

[172] Id. §§ 55052, 55051, 55040.

State Plant Board to prohibit or restrict the sale, cultivation, or other handling of rice that may have commercial impact (e.g., interfere with marketability in the event of commingling).[173] A Scientific Review Committee identifies rice varieties that may have commercial impact and recommends rules to govern planting, harvesting, sale, and other transactions involving those varieties.[174] A Missouri law enacted in 2004 authorizes voluntary grower districts. Missouri farmers who raise "agricultural crops for food, feed, industrial, and pharmaceutical uses" may create these districts.[175] A board of commissioners (owners or operators of cropland used to cultivate commercial crops) governs each district.[176] Districts have the potential to facilitate coexistence between GM and other crops.[177]

When these laws were enacted, only two varieties of GM rice had been deregulated in the US.[178] Concern about the impact of field trials of new varieties may have led to enactment of these laws, especially in Arkansas. Both California and Arkansas used their legislation to prevent field tests of GM rice after the accidental release of an unapproved GM variety (Bayer's LL601) caused disruption of trade.[179]

US producers also cultivate GM canola, and state measures authorize grower districts for rapeseed and canola. In Washington, requirements for growing *Brassica* in administratively established seed production districts help to prevent commingling of industrial rapeseed (for oil or fuel production) and food varieties of rapeseed (canola).[180] Similarly in Idaho, administrative regulations assign planting of industrial rapeseed and edible canola to different districts to minimize commingling.[181]

[173] Ark. Code Ann. §§ 2-15-201 to -208; see § 2-15-204(b)(1).

[174] Id. § 2-15-205(a). On the California and Arkansas laws, see Thomas P. Redick & Donald L. Uchtmann, Coexistence Through Contracts: Export-Oriented Stewardship in Agricultural Biotechnology vs. California's Precautionary Containment, 13 Drake J. Agric. L. 207, 227–229 (2008).

[175] Mo. Rev. Stat. § 261.256 (2012).

[176] Id. § 261.259.

[177] Redick & Uchtmann, supra note 174, at 238. By 2008, no district had been created,

[178] AgrEvo LLRice 06, LLRice 62. See USDA, Petitions for Determination of Nonregulated Status, http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml.

[179] Redick & Uchtmann, supra note 174, at 229, 232–33. LL601, similar to varieties already approved, was deregulated in 2006, 71 Fed. Reg. 70,360 (4 Dec. 2006). On the Bayer incident, see infra notes 272–276.

[180] Brassica Seed Production Districts, Wash. Admin. Code §§ 16-326-010 to 16-326-060 (2012).

[181] Idaho Admin. Code 02.06.13, authorized by Idaho Code § 22-108(2). Oregon also authorizes canola control areas. Or. Rev. Stat. §§ 570.405, 570.450 and Senate Bill 207 (introduced, Jan. 2015).

Local Bans

Several California counties have banned the cultivation of GM crops within their borders. Mendocino County was the first to ban GM crops, followed by Trinity, Santa Cruz, and Marin counties.[182] Efforts to enact bans in other California counties, including San Luis Obispo, Butte, and Sonoma, failed.[183] After failure of the 2004 proposal to ban GMOs in San Luis Obispo County, farmers in the county negotiated a compromise: a system that allowed farmers who grew GM crops to give notice to others by marking a map, so that neighboring farmers (organic and others) could take measures to protect their crop from contamination.[184] More recently, counties in Oregon and Hawaii banned GM production. Reacting to cultivation of GM sugar beets, Jackson County, Oregon enacted its Genetically Engineered Plant Ordinance to prohibit cultivation of genetically engineered plants in the county.[185] In Hawaii, Kauai County passed a ban on GM crops, and Maui County passed a moratorium. A federal judge held that state law preempted the Kauai County ban, and the Maui County litigation continues.[186] A few individual towns have also banned, or tried to ban, cultivation of GM crops.

Labeling of GM Food

Federal Law

The Food, Drug, and Cosmetic Act (FDCA)[187] and FDA regulations[188] govern food labels in the US. GM foods must comply with labeling requirements that apply to all foods, but the FDA does not require special labels for most GM foods.[189] The

[182] See e.g., Marin County, CA Code, ch. 6.92, Prohibition of Growing of Genetically Modified Crops (passed, 2004) (making cultivation of GM organisms a public nuisance).

[183] Redick & Uchtmann, supra note 174, at 229–231.

[184] McHughen, supra note 23, at 1109.

[185] Jackson County, Oregon, The Genetically Engineered Plant Ordinance (chap. 635, 2013). Josephine County, Oregon also approved a ban, but a state law (Or. Rev. Stat. § 633.738 (2013), enacted after Jackson County's ban was on the ballot) preempts local governments from governing GM crops. Farmers who produce GM alfalfa have challenged the ordinance. Schulz Family Farms LLC v. Jackson County, Case 1:2014cv01975 (D. Ct. Ore.).

[186] Kauai County, Hawaii Ordinance 960; Maui County, Hawaii, Ballot Initiative (Nov. 2014), codified at Maui County Code, chap. 20.39. Kauai has appealed to the 9th Circuit. The same judge has also invalidated the restriction on GM crops on the Big Island (Hawaii County Ordinance 13–121). Jennifer Sinco Kelleher, Federal judge rules against Big Island GMO law, Washington Times, 26 Nov. 2014.

[187] FDCA, supra note 117. The discussion of labeling is adapted in part from a book chapter to be published in Italy.

[188] 21 C.F.R. part 101, Food Labeling.

[189] FDA, 1992 Policy, supra note 131, at 22,991.

FDCA provides that food is "misbranded" if its label is "false or misleading,"[190] determined in part by "the extent to which the labeling … fails to reveal [material] facts."[191] The FDA interprets the term "material" to refer to attributes of the food product itself – e.g., a health risk. But methods used to develop new plant varieties, including GM food varieties, are not material information under the FDCA. The FDA was "not aware of any information showing that [GM foods] differ from other foods in any meaningful or uniform way, or that [GM foods] present any different or greater safety concern than foods developed by traditional plant breeding."[192] Therefore the agency believed that it had no basis to require GM foods to be labeled. Thus GM food products need not be labeled as GM unless the food itself differs materially from similar foods – e.g., in its nutritional content or by the presence of an allergen.[193]

A 2000 court decision upheld the FDA's interpretation of "material" and the resulting decision not to require labels for GM food.[194] Plaintiffs alleged that the FDA had failed to consider consumer interests in labeling and concerns of religious groups and people with food allergies;[195] the FDA responded that the FDCA did not authorize labels for GM foods only to respond to consumer demand. The court found the FDA's interpretation reasonable, noting that "it is doubtful whether the FDA would even have the power under the FDCA to require labeling in a situation where the sole justification for such a requirement is consumer demand."[196] If no material difference exists between GM and non GM foods, the court indicated, it would be misbranding to label the GM product as different. Because the FDA had determined that genetic modification does not alter foods materially, a determination to which the court granted deference, the FDA lacked a legal basis for requiring labels, even in the face of consumer demand.

In 2001, recognizing that some consumers want to know if food is genetically modified, the FDA published a draft guidance document on voluntary labeling of GM foods.[197] The document was intended to help industry ensure that voluntary labels are truthful and do not mislead consumers or suggest that foods that contain GMOs are inferior to GM-free foods. The draft guidance suggests language that

[190] 21 U.S.C. § 343(a).

[191] Id. § 321(n).

[192] FDA, 1992 Policy, supra note 131, at 22,991.

[193] Legal commentators suggest that Congress should require GM food to be labeled. See, e.g., Margaret Sova McCabe, Superweeds and Suspect Seeds: Does the Genetically-Engineered Crop Deregulation Process Put American Agriculture at Risk?, 1 U. Balt. J. Land & Dev. 109, 153–54 (2012); Debra M. Strauss, The Role of Courts, Agencies, and Congress in GMOs: A Multilateral Approach to Ensuring the Safety of the Food Supply, 48 Idaho L. Rev. 267, 315 (2012).

[194] Alliance for Bio-Integrity, supra note 151, at 179.

[195] Id. at 178.

[196] Id. at 179.

[197] FDA, Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance (2001), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm.

could be used on food labels without causing the label to be misleading and the food therefore misbranded. For example, "GMO free" is misleading and inaccurate, but other statements (e.g., "This product contains cornmeal that was produced using biotechnology.") are unlikely to mislead consumers.[198] By February 2015, the FDA had not yet finalized the draft guidance.

Several respected scientific organizations support the FDA decision not to require labeling.[199] The American Medical Association stated that "there is no scientific justification for special labeling of bioengineered foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education." Instead of labels, the AMA recommended science-based regulatory oversight and "mandatory pre-market systematic safety assessments of bioengineered foods."[200] The American Association for the Advancement of Science, noting that GM varieties are the "most extensively tested crops ever added to our food supply," stated that GM crops pose no special risk, and that required labels "can only serve to mislead and falsely alarm consumers."[201] Legal scholars disagree about the need for GM labels. In the absence of legitimate scientific concerns, however, one high-profile scholar argued against compulsory GM labels, in part because they may spread alarm and discourage retailers from making GM products available.[202]

Consumer sentiment is mixed. A nationally representative survey conducted in 2014 indicated that 63 % of consumers "support the current FDA policy for labeling of foods produced through biotechnology" that requires labels only for changed nutritional content or composition and food safety issues.[203] Of the 26 % of consumers who wanted additional information on food labels, most wanted enhanced nutritional information, and only 4 % mentioned biotechnology.[204] Other surveys, however,

[198] Id. (all quotations).

[199] See Council for Agricultural Science and Technology (CAST), The Potential Impacts of Mandatory Labeling for Genetically Engineered Food in the United States (Issue Paper 54, CAST, Ames, Iowa, 2014) (analyzing legal and economic implications of mandatory labeling and recommending against mandatory labeling).

[200] American Medical Assoc., Policy H-480.958: Bioengineered (Genetically Engineered) Crops and Foods (June 2012) (all quotations). But see American Public Health Association, Policy Statement 2001–11, 92(3) Am. J. Pub. Health 451, 463 (2002) ("any food product containing genetically modified organisms [should] be so labeled").

[201] AAAS, Statement by the AAAS Board of Directors on Labeling of Genetically Modified Foods (2012), http://www.aaas.org/news/releases/2012/media/AAAS_GM_statement.pdf. The AAAS statement engendered controversy and disagreement. See also Editorial, Fight the GM Food Scare, supra note 90.

[202] Cass Sunstein, Don't Mandate Labeling for Gene-Altered Foods, Bloomberg, 12 May 2013. See Gary E. Marchant & Guy A. Cardineau, The labeling debate in the United States, 4(3) GM Crops & Food: Biotec. Agric. & Food Chain 126,133 (2013): "The GM labeling debate is one of the most important battlefields in the country pitting science- and evidence-based public policy against a populist social movement funded and manipulated by pseudoscientific, unaccountable and self-interested forces."

[203] IFIC, 2014, supra note 29.

[204] Id. Of millennials (ages 18–34), 39 % wanted additional information; 37 % wanted nutritional information, and 22 % wanted information about biotechnology.

vary. In a 2013 New York Times survey, 93 % of Americans polled believed that foods with GM ingredients should be identified.[205] An October 2013 survey found that only 7 % of respondents mentioned the need for GM food labeling on their own; when asked specifically about labels for GM foods, 73 % of consumers favored labels.[206]

Proponents of labeling have introduced bills in the US Congress, submitted petitions to the FDA, and communicated with the President. For example, a bill introduced in 2013 and reintroduced in 2015 would amend the FDCA, making GM food or food with GM ingredients misbranded, unless GM content is disclosed clearly, pursuant to regulations the FDA would be directed to enact.[207] Another, introduced in 2014, would authorize FDA regulations to govern voluntary labels to indicate whether food is bioengineered or not, require FDA regulations to govern "natural" claims on food, and preempt some state and local requirements.[208] By February 2015, however, Congress had not required labeling. Proponents of labeling also petitioned the FDA to require labels for GM foods, an effort supported by some members of Congress.[209]

State Labeling

Most states govern some aspect of biotechnology, and a few state laws, enacted in the early 2000s, require labeling of GM products – e.g., GM seed[210] or GM fish and their products.[211] One state enacted voluntary guidelines, so that products that contain 1 % or less of GM ingredients can be labeled as free of genetic engineered ingredients.[212]

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[205] Allison Kopicki, Strong Support for Labeling Modified Foods, NY Times, 27 July 2013.

[206] Hallman et al., supra note 25, at 4. The 7 % response was to the question, "What information would you like to see on food labels that is not already there?"

[207] Genetically Engineered Food Right-to-Know Act, S. 809 & H.R. 1699, 113th Congress; Safe and Accurate Food Labeling Act of 2014, H.R. 4432, https://www.congress.gov/bill/113th-congress/house-bill/4432

[208] The 2014 bill would have required premarket biotechnology notification before a GM food is introduced into interstate commerce. Both soybean and corn growers supported the 2014 bill, because it would "protect consumers and ensure the safety of food ingredients using solid science-based information by providing a consistent, informative GMO labeling solution that eliminates confusion and advances food safety." Press Release, National Corn Growers Association NCGA Announces Support [for] Federal GMO Labeling Legislation (9 Apr. 2014).

[209] FDA, Docket FDA-2011-P-0723-0001, http://www.regulations.gov. The FDA received comments on the petition, but had not responded by February 2015. In January 2014, 2000 food groups and others wrote to the President, demanding labels for GM foods.

[210] E.g., Vt. Stat. Online, tit. 6, §§ 611(c), 644(a)(4). Virginia's requirement, Va. Code § 3.1-275.4, was repealed in 2008.

[211] Alaska Stat. § 17.20.040(a)(14) (GM fish are misbranded unless conspicuously labeled).

[212] Me. Rev. Stat. tit 7 § 530-A (effective 1 Jan. 2002).

Recently, however, state focus on labeling has intensified, with both legislative action and citizen initiatives. According to one organization, 20 state legislatures have pending legislation that would require labeling of GM foods or ingredients.[213] Not all legislative efforts have been successful. In 2014, for example, legislatures in New Hampshire and California rejected labeling bills.[214] New York legislators failed to pass a labeling bill in 2013 and 2014, and a study indicated that the proposed law would raise annual food costs for a family of four by $500–$800.[215]

Three state legislatures enacted right to know laws. Connecticut's law, An Act Concerning Genetically-Engineered Food,[216] enacted in June 2013, will take effect only after four other states, including one bordering Connecticut, enact similar laws, and the total population of states in the Northeast with such laws exceeds 20 million. The law will require GE food and seed to be labeled, clearly and conspicuously, "Produced with Genetic Engineering."[217] Food without required labels will be considered misbranded, and food that is genetically engineered cannot be considered "natural food."[218] In Maine a disclosure statute for GE food and feed stock became law in January 2014 without the governor's signature. Under that measure, food is misbranded unless the genetically engineered content is disclosed. Until 1 July 2019, however, processed food is not misbranded if the total weight of GE ingredients is less than 0.9 % of the food. The Maine law also prohibits the use of the term "natural" for GE food.[219] Like the Connecticut law, the Maine law will take effect only after other states require labeling. In May 2014, Vermont enacted a law, Labeling of Food Produced with Genetic Engineering, that will take effect in July 2016, without regard to the actions of other states.[220] The Vermont law requires labels for food produced entirely or in part from genetic engineering, and prohibits the use of the term "natural" for GE food. It exempts some foods (including foods with an aggregate GE content of no more than 0.9 %), and it provides a temporary exemption for milk and milk products. The Grocery Manufacturers Association and others have challenged the Vermont law in federal court on constitutional and other grounds.[221]

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[213] Right to Know GMO, State Map, http://www.righttoknow-gmo.org/states (map with links to information about state legislation). For the status of GM labeling initiatives in various states, see CAST, supra note 199, at 11–13.

[214] E.g., California SB 1381; New Hampshire HB 660, http://legiscan.com/NH/bill/HB660/20134.

[215] William Lesser, Costs of Labeling Genetically Modified Food Products in N.Y. State (2014), http://dyson.cornell.edu/people/profiles/docs/LabelingNY.pdf.

[216] Pub. L. 13–183, effective 1 Oct. 2013, http://www.cga.ct.gov/2013/ACT/pa/pdf/2013PA-00183-R00HB-06527-PA.pdf.

[217] Id. § 3.

[218] Id. § 1.

[219] LD 718, 126th Maine Legislature, codified as Me. Rev. Stat. tit. 22, chap. 565.

[220] Act 120, codified at Vt. Stat. Ann. tit.9, chap. 82A. In October 2014, the state asked for public comment on draft rules to implement the law. The attorney general was to recommend whether milk or milk products must be labeled under the law. See International Dairy Foods Association v Amestoy, 92 F.3d 67 (2d Cir. 1996).

[221] Grocery Mfrs Ass'n v. Sorrell, No. 5:14-CV-117 (D. Vt.).

Citizens have proposed ballot initiatives in several states; if approved by voters, these initiatives become state law. In 2002, voters defeated an Oregon initiative to require GM labels. In a letter to the Governor, the FDA objected to the state ballot initiative, emphasizing the agency's scientific judgment that bioengineered foods are not significantly different from, and are as safe as, conventional foods. Moreover, state labeling would impede "the free flow of commerce between the states" and might mislead consumers.[222]

Recent ballot initiatives have also failed. In November 2012, California voters narrowly (53.1–46.9 %) defeated a hotly-contested ballot initiative opposed by biotechnology and food companies. Intended to inform people about genetically engineered ingredients and allow freedom of choice, the California Right to Know Genetically Engineered Food Act would have required "clear and conspicuous" disclosure of genetically engineered food or food ingredients.[223] It would also have restricted the use of the word "natural" and related terms on product labels of GE food and (even minimally) processed food. Food that did not comply with the requirements would have been misbranded under California law. Similarly, in 2013, voters defeated an initiative in the state of Washington, supported by organic and other farmers, that would have required labeling for food produced entirely or partly with genetic engineering.[224] Voters also rejected initiatives in Colorado and Oregon in the November 2014 election.[225]

Constitutional Issues

State labeling requirements, whether enacted legislatively or by ballot initiative, may raise significant legal issues.[226] Although states retain sovereignty to enact laws under the Tenth Amendment to the US Constitution,[227] other constitutional

[222] Lester M. Crawford, FDA Deputy Commissioner, Letter to Oregon Governor John A. Kitzhaber, 4 Oct. 2002, http://www.bio.org/sites/default/files/Kitzhaber_0.pdf.

[223] The California Constitution, art. II, § 8, allows ballot initiatives under which the people of the state enact laws. The text of Proposition 37 is available in Text of Proposed Laws 110, http://vig.cdn.sos.ca.gov/2012/general/pdf/text-proposed-laws-v2.pdf (2012).

[224] Washington, Initiative Measure No. 522 (filed June 29, 2012), http://sos.wa.gov/_assets/elections/initiatives/FinalText_285.pdf.

[225] Colorado, Proposition 105 (filed Nov. 22, 2013) (70 % of voters opposed), http://www.sos.state.co.us/pubs/elections/Initiatives/titleBoard/filings/2013-2014/48Final.pdf; Oregon, Measure 92 (filed 3 Jan 2014), http://ballotpedia.org/Oregon_Mandatory_Labeling_of_GMOs_Initiative,_Measure_92_(2014),_Full_text_of_measure.

[226] See Margaret Rosso Grossman, California Proposition 37: Voters Reject Mandatory Labeling of GM Food, 8(1) Eur. Food & Feed L. Rev. 73 (2013). See generally Laura Murphy et al., More than Curiosity: The Constitutionality of State Labeling Requirements for Genetically Engineered Foods, 37 Vt. L. Rev. 477–553 (2013) (drawn from a memorandum to support GM labeling legislation in Vermont).

[227] U.S. Const. amend. X: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

doctrines, as well as federal laws and regulations, may limit state authority to require labels on GM food.[228]

State labeling laws are vulnerable to challenge under the Dormant Commerce Clause. Under the Commerce Clause of the US Constitution, Congress has authority "to regulate commerce … among the several states."[229] Even when Congress has not regulated, the Dormant Commerce Clause prohibits states from enacting laws that discriminate against, or unduly burden, interstate commerce. In the absence of a federal labeling requirement, state laws are likely to burden interstate commerce, e.g., by requiring food manufacturers in other states to comply with the state labeling law or stop selling unlabeled GM foods in the state. The Dormant Commerce Clause doctrine is complex and nuanced, and the result of a challenge depends on the language of the state labeling law, the nature of the state interest (to protect health or only to satisfy consumer curiosity?), and the degree of burden (including economic) on interstate commerce. If the state law serves a legitimate public interest, the extent of the burden on commerce is relevant. As a leading decision indicated, "the extent of the burden that will be tolerated will … depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities."[230]

The First Amendment, which protects both the freedom to speak and the right not to speak, poses another constitutional challenge.[231] Because the First Amendment does not fully protect commercial speech, states can regulate commercial speech if their interest in regulation is substantial and the regulation is narrowly tailored to advance that interest.[232] States may also require disclosures to prevent deception of consumers.[233] Whether state-compelled disclosure of GM food ingredients prevents deception is a matter of disagreement, however, in light of the FDA's conclusion that GM foods are not materially different from their conventional counterparts. The decision in a successful challenge to a state law that required labeling of dairy products from cows treated with recombinant Bovine Somatotropin (rBST) may provide

[228] State labeling laws may affect international trade and may violate WTO Agreements. For a detailed analysis see Drew L. Kershen, Would State-Mandated Labels for Biotech Foods Violate World Trade Agreements? (Washington Legal Foundation, 2012).

[229] U.S. Const. art. I, § 8, cl. 3.

[230] Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970). See John S. Harbison, The War on GMOs: A Report from the Front, at 13–16 (2004), link from http://www.NationalAgLawCenter.org.

[231] U.S. Const. amend. I: "Congress shall make no law … abridging the freedom of speech." See generally Pamela A. Vesilind, Emerging Constitutional Threats to Food Labeling Reform, 17 Nexus: Chap. J. L. & Pol'y 5 (2012).

[232] States can regulate misleading commercial speech or speech that concerns unlawful activity. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557, 566 (1980). The prohibition of claims that GE foods are natural, as in the Connecticut and Maine laws, may violate the First Amendment. See Lauren Handel, Labeling of Genetically Engineered Foods: A Constitutional Analysis of California's Proposition 37, at 4–7 (2012), http://ssrn.com/abstract=2169440.

[233] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985).

insight.[234] The court characterized the law as requiring "the functional equivalent of a warning about a production method that has no discernible impact on a final product," and held that "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement."[235] Nonetheless, the US Supreme Court has recognized the importance of providing information and noted that the "constitutionally protected interest in not providing any particular factual information … is minimal," especially when disclosure requirements are not unduly burdensome.[236]

The doctrine of preemption, based on the Supremacy Clause,[237] may also pose challenges to state-required GM labels. The doctrine establishes the extent of federal authority to exclude states from an area of legislation; preemption normally applies when Congress has the authority to act and indicates its intention to exclude state law. Federal food laws include preemption language. One analysis concluded that under current law, state statutes that require labels for GM foods are likely to be preempted for meat and poultry products, but not for other GM foods.[238] Preemption provisions in the FDCA that affect food labels apply to specific types of label information (e.g., nutrition or health claims),[239] but not to GM foods. Therefore state label requirements for most GM foods are not likely to be preempted, as long as federal law does not govern GM food labels. But preemption may prohibit state-required disclosures of GM content in foods for which the FDA has established comprehensive labeling standards.[240] In contrast, federal laws that govern labels for meat and poultry products preempt state labeling requirements in addition to, or different from, federal requirements.[241] Because the USDA does not require labels to disclose GM content of meat and poultry, state requirements are likely to be preempted. Of course, the US Congress can enact new laws to preempt or to permit state labeling requirements.

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[234] Amestoy, supra note 220.

[235] Id. at 73, 74.

[236] Zauderer, supra note 233, at 651. See Handel, supra note 232, at 7–10.

[237] U.S. Const. art. VI, cl. 2: "This Constitution, and the Laws of the United States … shall be the supreme Law of the Land."

[238] Handel, supra note 232, at 10–13 (analyzing preemption provisions that apply to FDA and USDA regulation).

[239] 21 U.S.C. § 343–1 (preempting some types of labeling required by 21 U.S.C. § 343).

[240] E.g., GM canola oil, for which FDA labeling standards exist. See Briseno v. ConAgra Foods, Inc., 2011 U.S. Dist. Lexis 154750 (C.D. Cal.) (dismissing plaintiff's demand for disclosure of GM ingredients in canola labeled "100 % Natural").

The National Corn Growers Association opposes state labeling mandates and supports "FDA having federal preemption of individual state labeling laws." NCGA, Biotechnology, in 2013 Policy and Position Papers 8, 10 (No. 1-A-1, 2013).

[241] Federal Meat Inspection Act, 21 U.S.C. §§ 601–692, at § 678; Poultry Products Inspection Act, 21 U.S.C. §§ 451–471, at § 467e.

"Natural" Labels

Use of the term "natural" on labels of food products that contain GM ingredients is controversial. Although many products are labeled as natural (or variations of that term), FDA regulations do not define the term. In its 1993 food labeling rulemaking, the FDA decided not to offer a definition, but to continue to use "natural" to mean "nothing artificial or synthetic … has been included in, or has been added to, a food that would not normally be expected to be in the food."[242] Because the FDA definition is not regulatory, however, it does not have the force of law.[243] Therefore, courts have held that challenges to natural label claims are not preempted because the FDA has not defined natural by regulation.[244]

Plaintiffs in dozens of recent cases have alleged that products labeled natural are marketed deceptively when those products contain GM ingredients.[245] In May 2013, a federal district court held that federal regulations did not preempt a state-law challenge, when soup labeled "100 % Natural" included GM corn.[246] Although courts have declined to dismiss such cases under the doctrine of primary jurisdiction, a few judges referred the question of the use of the term natural for products with GM ingredients to the FDA for an administrative determination.[247] The FDA,

[242] FDA, Food Labeling: Nutrient Content Claims, 58 Fed. Reg. 2302, 2407 (6 Jan. 1993). See also id. at 2397: "FDA has decided not to define the term 'natural' or to prohibit its use." See Erik Benny, Essay, "Natural" Modifications: The FDA's Need to Promulgate an Official Definition of "Natural" that Includes Genetically Modified Organisms, 80 Geo. Wash. L. Rev. 1504, 1521–1525 (2012) (asserting that GM food meets FDA's informal definition of natural, because it has no synthetic or artificial ingredients).

The USDA has a policy on use of the term natural on labels for meat and poultry. An applicant for labeling must show that the product does not contain artificial or synthetic ingredients and that the product and its ingredients are "not more than minimally processed." FSIS, USDA, Food Standards and Labeling Policy Book, at 116 (2005).

[243] Holk v. Snapple Beverage Corp., 575 F.3d 329, 342 (3d Cir. 2009) (holding that state consumer fraud class action challenging "all natural" for beverages made with high fructose corn syrup is not preempted).

[244] E.g., a California district court issued an order that preliminarily certified a $4 million settlement in a case involving snack items, cereals, and other foods marked "all natural" but containing GM, artificial, and synthetic ingredients. Trammell v. Barbara's Bakery, Inc., No. 12–2664 (N.D. Cal., 26 June 2013). A $9 million settlement resolved five class action suits concerning juice with GM ingredients. Pappas v. Naked Juice Co., No. LA CV 11-08276-JAK (PLAx) (C.D. Cal., 7 Aug. 2013). See http://www.nakedjuiceclass.com. Parties have settled other cases.

[245] E.g., In re Wesson Oil Marketing and Sales Practices Litigation, 818 F. Supp. 2d 1383 (J.P.M.L. 2011) (consolidating six cases); In re Conagra Foods, Inc., 2013 WL 4259467 (C.D. Cal.) (denying stay pending outcome of referral to FDA).

[246] Krzykwa v. Campbell Soup Co., 2013 WL 2319330 (S.D. Fla.).

[247] E.g., Cox v. Gruma Corp., 2013 WL 3828800 (N.D. Cal.). The Organic Consumers Association petitioned the FDA to prohibit the use of the term natural for products with GM ingredients. Press Release, Organic Consumers Association, OCA Asks FDA to Prohibit Use of the Word 'Natural' in Products Containing GMOs (14 Aug. 2013), link from http://www.organicconsumers.org. The Grocery Manufacturers Association planned to petition the FDA to allow GM foods to be labeled natural. Letter from Karin F.R. Moore, GMA, to Elizabeth H. Dickinson, FDA, 5 Dec. 2013; Stephanie Strom, Group Seeks Special Label for Food: 'Natural,' NY Times, 19 Dec. 2013.

however, declined to make a determination "in the context of litigation between private parties."[248] The FDA prefers to address the complex issue of the use of the term natural, which has broader implications than only GM foods, by regulation or formal guidance. The agency's limited resources, however, mean that other matters take higher priority.

Voluntary Labeling

Private voluntary efforts to lable GM food exist. For example, Whole Foods Market announced that by 2018, all GM foods sold in its US and Canadian stores would require labels that disclose the presence of GM ingredients. Whole Foods took this step in response to consumer demands for labeling. It already offers about 3300 products that meet the requirements of the Non-GMO Product Verification Program, which establishes best practices to avoid GM content and provides a seal of approval.[249] The Non-GMO Project, the leading US third-party verification system, evaluates products, ingredients, and facilities for compliance with its Non-GMO Project Standard.[250] Its certification program also applies to meat products. In June 2013, for the first time, USDA's Food Safety Inspection Service approved a voluntary non-GMO label for meat and liquid egg products from animals raised without GM feeds. The agency approved the label, which included the Non-GMO Project certification seal, only after investigating the Non-GMO Project's certification requirements to ensure that claims on the meat labels would be "truthful, accurate, and not misleading."[251]

Some restaurants plan to eliminate GM foods or provide information to customers. For example, the Chipotle chain, which informs consumers about GM content of its foods on its website, is moving to non-GM foods (e.g., sunflower instead of soybean oil).[252] McDonald's announced that it will not use a newly authorized GM potato, which will reduce a carcinogenic ingredient produced in making fries, because it prefers to avoid GMOs.[253]

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[248] Letter from Leslie Kux, FDA Assistant Commissioner for Policy, to the Honorable Yvonne Gonzalez Rogers et al., 6 Jan. 2014.

[249] Cookson Beecher, Whole Foods to Require Labeling of GM Foods, Food Safety News, 15 Mar. 2013, http//www.foodsafetynews.com.

[250] Version 11 of the Standard (ratified May 2014) is at http://www.nongmoproject.org/wp-content/uploads/2014/06/Non-GMO-Project-Standard-v11.pdf. Since 2010, the Non-GMO Project has certified almost 25,000 products See Stephanie Strom, Many G.M.O.-Free Labels, Little Clarity Over Rules, N.Y. Times, 30 Jan. 2015.

[251] Stephanie Strom, U.S. Approves a Label for Meat From Animals Fed a Diet Free of Gene-Modified Products, N.Y. Times, 20 June 2013.

[252] Chipotle, Ingredients Statement, GMOs, link from http://www.chipotle.com ("Our goal is to eliminate GMOs from Chipotle's ingredients.").

[253] Chuck Jolley, McDonald's says No to GMOs (19 Nov. 2014) link from http://feedstuffsfoodlink.com. USDA authorized the potato, developed by J.R. Simplot, in 2014.

Liability

The regulatory framework for GMOs and GM foods does not assign liability for damages that might be caused by their cultivation and use. Those who develop GMOs are obligated by the provisions of federal laws and regulations that govern authorization. Failure to comply with regulatory requirements may result in penalties established by statute.[254] Producers who cultivate GM crops will be subject to contract obligations imposed by the crop developer, often to protect intellectual property rights. Developers enforce these rights in litigation against producers who violate contract obligations and against others whose crops are found to contain patented varieties, even unintentionally.[255]

Liability in Tort

In addition to regulatory and contract obligations, GMOs may trigger liability in tort under state common-law principles or statutes. Up to now, discussions of tort liability have focused primarily on seed companies and farmers, with little focus on liability associated with GM food. Producers or purchasers of non-GM, organic, or identity-preserved varieties may assert claims for losses caused by cross-pollination or commingling.[256] Gene transmission (pollen drift) or commingling may result in contained liability, but more catastrophic damage can occur. GM developers or seed companies face significant damages if GM "events" not yet approved in the US, or approved in the US but not by trading partners, commingle with other crops and enter the chain of commerce. Purchasers may consider those crops "contaminated," and economic consequences follow. Courts, however, rarely allow plaintiffs to recover for consequences involving "pure economic loss" (damages unrelated to injury to property or physical loss), such as loss of export markets.[257]

US court decisions have recognized tort causes of action from release of unapproved GMOs.[258] Plaintiffs who claim damages from GM crops may sue in

[254] This discussion does not consider cases (e.g., alfalfa, bentgrass) that allege failure of USDA to prepare an environmental impact statement under the National Environmental Policy Act. See supra note 114.

[255] See Debra M. Strauss, Liability for Genetically Modified Food: Are GMOs a Tort Waiting to Happen?, SciTech Law. 8, 9 (Fall 2012) (discussing Monsanto's patent infringement cases).

[256] Damage from cross-pollination is not theoretical. "The scientific evidence of the propensity of GM genes to wander – and to wander further than initially thought – is piling up." Jane Matthews Glenn, Footloose: Civil Responsibility for GMO Gene Wandering in Canada, 43 Washburn L.J. 547, 547 (2004).

[257] See Grossman, supra note 168, at 330–331.

[258] E.g., In re StarLink Corn Prods. Liab. Litig., 212 F. Supp. 2d 828 (N.D. Ill. 2002).

nuisance, trespass, negligence, or strict liability (or a combination).[259] In any of these causes of action, determining liability for the harm caused by GMOs requires proof of causation (e.g., the source of GM cross-pollination or commingling), which may pose difficulties. Remedies include damage awards and (less often) full or limited injunctions against the defendant's activities.

Nuisance law provides a remedy when a defendant's activities interfere unreasonably with plaintiff's use and enjoyment of land, cause death, harm health, or interfere with public rights.[260] The existence of a nuisance is a question of fact and often requires the court to balance the interests of the parties. Private nuisance is an interference with plaintiff's use and enjoyment of land, while public nuisance interferes with land use of a large number of persons or with public rights.[261] Nuisance can be intentional or negligent. Intentional nuisance requires that plaintiff suffered substantial and unreasonable interference with the use of property and that defendant have knowledge (sometimes called "civil intent") that its activities were likely to injure plaintiffs. Negligent nuisance requires proof that defendant's activities themselves were unreasonable.[262] For claims of damage from GMOs, plaintiffs may prefer to allege intentional nuisance; planting authorized GM crops is unlikely to constitute the unreasonable behavior required to prove negligent nuisance. The doctrine of anticipatory nuisance may prevent serious threatened harm from GMOs. Under this doctrine, the plaintiff seeks an injunction to prevent future harm from a defendant's proposed activity, when that activity is almost certain to cause substantial damage.[263]

Trespass requires an invasion of real property that interferes with the plaintiff's exclusive possession and causes damage to that property. The presence of unwanted GM pollen on neighboring land may give rise to a claim in trespass.[264]

A claim of negligence usually requires the plaintiff to prove that the defendant had a duty to conform to a specific standard of conduct (normally, to exercise reasonable care under the circumstances), that the defendant breached that duty, that the plaintiff suffered harm, and that the defendant's breach of duty was the

[259] For more detailed discussion, see Grossman, supra note 168, at 321–331. See also Paul J. Heald & James Charles Smith, The Problem of Social Cost in a Genetically Modified Age, 58 Hastings L.J. 87 (2006). See also In re StarLink Corn Prods., supra note 258.

[260] A nuisance is an activity or condition that is harmful, annoying, offensive, unpleasant, disagreeable, or inconvenient to another. Restatement (Second) of Torts § 821A cmt. b (1979).

[261] Id. § 822 cmts. c & d.

[262] Zygmunt J.B. Plater et al., Environmental Law and Policy: Nature, Law, and Society, at 75 (4th ed. 2010).

[263] For a detailed discussion, see Margaret Rosso Grossman, Anticipatory Nuisance and the Prevention of Environmental Harm and Economic Loss from GMOs in the United States, 18 J. Envtl L. & Prac. 107–167 (2008).

[264] Drew L. Kershen, Legal Liability Issues in Agricultural Biotechnology, 10 Envtl Liab. 203, 205–207 (2002). Trespass by GM pollen may not meet an old requirement of a "direct and immediate" invasion because of the passage of time (pollination occurs long after planting) and the intervening force of wind. Heald & Smith, supra note 259, at 135.

proximate cause of plaintiff's injury.[265] The plaintiff who claims negligence must therefore prove that the defendant's actions with the GM crops were unreasonable.

Strict liability applies in situations when the defendant, even a defendant who acted with reasonable care, causes injury in the course of an activity characterized as abnormally dangerous or ultrahazardous.[266] Planting a fully-authorized GM variety, however, seems unlikely to constitute an ultrahazardous activity.

Some Examples of Liability

To foster practices that prevent commingling and avoid legal claims, the seed industry, including the American Soybean Association (ASA) and the National Corn Growers Association (NCGA), developed stewardship programs. Motivated by the threat of liability to farmers it represents, the ASA asked seed companies not to sell unapproved varieties commercially and established requirements for preserving the identity of unapproved GM soybeans.[267] The NCGA urged members to minimize trade disruptions by being aware of the approval status of corn hybrids and by selling hybrids not approved in the EU and other important trading countries into domestic, rather than export, markets.[268]

When industry stewardship fails, or harm results from the activities of seed companies or producers, damages and lawsuits may result. Several accidental releases of GM plants and seeds during recent years illustrate. Well-publicized incidents involved StarLink corn, ProdiGene corn, LibertyLink rice and, in 2013, MON71800 wheat. Commercialization of crops not yet approved by important trading partners (asynchronous approval) has also resulted in litigation.

In 2000, StarLink corn, developed by Aventis CropScience and approved only for feed and industrial uses, was found in food products for human consumption, resulting in recalls and trade disruption. *In re StarLink Corn Products Liability Litigation*,[269] a class action lawsuit, included common law tort claims for damages. The judge held that the case could be tried on claims of negligence and private and public nuisance. Those tort claims were not adjudicated in *StarLink*, however,

[265] See Kershen, supra note 264, at 208–210, for a discussion of negligence.

[266] Restatement (Second) of Torts § 520 & cmt. f (1977).

[267] American Soybean Association, Policy Resolution on Biotechnology Approvals and Minimum Requirement for Attempted Identity-Preserved Production, Harvesting, and Utilization of Biotechnology-enhanced Varieties/Hybrids that are Unapproved for Export to Major Markets (2000).

[268] NCGA, Know Before You Grow (2013), http://www.ncga.com/for-farmers/know-before-you-grow/trait-table (listing GM corn varieties and their approval status in the EU and Japan). See also NCGA, Biotechnology, supra note 240.

[269] 212 F. Supp. 2d 828 (N.D. Ill. 2002).

because the parties settled the issues before trial. Nonetheless, the settlement and efforts to contain the GM corn cost Aventis millions of dollars.[270]

The 2002 ProdiGene incident resulted from a field trial of a pharmaceutical corn crop that produced a diagnostic protein (avidin). After harvest, the field was planted with soybeans (in violation of USDA's requirement that the field be left fallow). Some kernels of pharma corn in the field germinated as volunteers and contaminated the soybeans, intended for human consumption. The USDA required destruction of the contaminated soybeans, and the agency required ProdiGene to pay $3 million in compensation and a $250,000 fine.[271]

LibertyLink rice (LLRice 601) was an herbicide-resistant test variety developed by Bayer CropScience. In 2006, before the rice was approved for human consumption, the detection of trace amounts in the US rice supply disrupted trade, and rice prices declined.[272] Numerous lawsuits, filed in federal court, were transferred to a US District Court in Missouri. In the first trial, with claims in negligence and private nuisance, a jury awarded the farmers and other plaintiffs more than $2 million in compensatory damages.[273] Other cases followed, and by August 2010, Bayer had lost in six jury trials, and some cases had been settled.[274] About 300 federal cases, with claims from 5000 plaintiffs, were pending, and 2000 plaintiffs sued in state courts.[275] In July 2011, Bayer entered a $750 million settlement with 11,000 farmers to resolve claims of contamination.[276]

No GM wheat varieties have been approved for sale in the US. Therefore, the May 2013 discovery of volunteer GM wheat in an isolated field in Oregon again slowed trade and triggered litigation. The FDA had concluded a voluntary food safety consultation for the wheat, and USDA had authorized Monsanto to conduct field tests on the variety (MON71800). Investigation into the incident found no

[270] Aventis voluntarily cancelled the registration for StarLink. Aventis formed a corporation to monitor corn to contain the GM protein; these efforts succeeded, and monitoring ended in 2008. US EPA, White Paper Concerning Dietary Exposure to Cry9c Protein Produced by StarLink Corn and the Potential Risks Associated with Such Exposure (2008). For more detail see Grossman, supra note 168, at 331–333.

[271] Federation of American Scientists, The Prodigene Incident, http://www.fas.org/biosecurity/education/dualuse-agriculture/2.-agricultural-biotechnology/prodigene-incident.html.

[272] The USDA deregulated the rice, but farmers and others had already suffered damages. APHIS, Notice, 71 Fed. Reg. 70,360 (4 Dec. 2006).

[273] Joe Whittington & Andrew M. Harris, Bayer Must Pay Farmers for Contaminated Rice Crop, Bloomberg, 4 Dec. 2009. The judge had granted defendant Bayer's motion for summary judgment on public nuisance, negligence per se, and other claims, but held that the economic loss doctrine did not bar plaintiffs' tort claims. In re Genetically Modified Rice Litigation, 666 F. Supp. 2d 1004, 1015–1017 (E.D. Mo. 2009) (motions for summary judgment).

[274] E.g., Ruling compensates farmers for GM rice contamination, Greenwire, Feb. 8, 2010; Jury Tells Bayer to Pay Ark. Rice Farmers $48 M, Bloomberg, 15 Apr. 2010.

[275] In re Genetically Modified Rice Litigation, 2010 WL 716190 (E.D. Mo. 2010) (memorandum and order concerning proposed trust fund).

[276] Andrew Harris & David Beasley, Bayer Agrees to Pay $750 Million to End Lawsuits Over Gene-Modified Rice, Bloomberg, 1 July 2011.

evidence of the GM wheat beyond one field on one farm, and its source remains uncertain.[277] Nonetheless, lawsuits against Monsanto allege nuisance, negligence and strict liability in its field trials.[278]

Asynchronous approvals, which can cause disruption of markets, have also led to litigation. A recent example involves Syngenta's Agrisure Viptera corn, genetically engineered to control insects. Viptera was approved by the USDA in 2010 and cultivated since 2011. China had not yet approved Viptera,[279] and in 2014, after US corn shipments contained traces of Viptera, China banned the import of US corn, resulting in significant trade losses – perhaps as many as 131 million bushels. As of January 2015, farmers and others had filed more than 360 lawsuits, alleging financial losses (as much as $3 billion) from China's rejection of US corn.[280] Litigation against Syngenta has been consolidated in federal court in the US District Court in Kansas, and additional cases are likely.[281]

As these examples indicate, controversies about liability so far have focused on release of unauthorized varieties and asynchronous approvals, rather than issues of food safety. But commentators noted that "beyond the financial losses that GM crop production could cause, one can question whether there can be liability on the part of GM producers and users should the release of this biotechnology into the environment be proven to cause injury to human health or the ecosystems."[282] Moreover, if the federal government or states require GM foods to be labeled, those laws may engender other issues and liability claims. Failure to comply with labeling requirements may result in penalties for misbranding, and claims under state or federal consumer fraud laws may be possible.[283]

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[277] Press Release, USDA, Update on the Detection of Genetically Engineered (GE) Glyphosate-Resistant Wheat Plants (29 July 2013). In September 2013, a low level of GM alfalfa was discovered in a Washington farmer's non-GM alfalfa. USDA planned no government action, calling the contamination a "commercial issue." Carey Gillam, USDA will not take action in case of GMO alfalfa contamination, Reuters, 17 Sept. 2013.

[278] E.g., Center for Food Safety v. Monsanto, No. 13–213 (E.D. Wash., filed 5 June 2013). See http://www.centerforfoodsafety.org.

[279] Agrisure Viptera was approved in China in December 2014. See Syngenta's website, http://www.syngenta-us.com/Agrisure/agrisure-viptera.aspx.

[280] David Pitt, Farmers File More Than 360 Corn Lawsuits Against Syngenta, Associated Press, 6 Feb. 2015, http://abcnews.go.com/US/wireStory/farmers-file-360-corn-lawsuits-syngenta-28777413. Farmers who did not plant Viptera, but whose corn could not be exported to China, sued, as did large exporting companies.

[281] Transfer Order, In Re Syngenta AG MIR 162 Corn Litigation – MDL No. 2591 (11 Dec. 2014).

[282] Lara Khoury & Stuart Smyth, Reasonable Foreseeability and Liability in Relation to Genetically Modified Organisms, 27 Bul. Sci. Tech. & Soc. 215, 221 (2007). Harms to human health have not been identified.

[283] Cases involving GM components of foods labeled "natural" have already raised the fraud issue. See supra text accompanying notes 242–248.

Conclusion

In light of expected increases in the world's population by 2050, coupled with the effects of climate change on the environment and agricultural production, 16 well-known international scientists emphasized that GM varieties will be critical for food security in the twenty-first century.[284] Genetic modification, along with conventional breeding, will help "to adapt our existing food crops to increasing temperatures, decreased water availability in some places and flooding in others, rising salinity, and changing pathogen and insect threats"; GM crops can increase nitrogen uptake and efficiency to protect waterways and decrease greenhouse gas emissions.[285]

Moreover, an influential report insists on the relationship between biotechnology and environmental protection: "[t]he world needs a new US agenda for global food security focused on science, trade, and business," using a concept called "sustainable intensification."[286] Both conventional breeding and biotechnology, as well as other tools, play a role in this new agenda. The report pleads for public investments in agricultural research, in part because "[b]iotechnology for the smallholder farmer … requires public involvement."[287] If small farmers in developing countries lack access to technological innovations, "it may not be possible to meet future demand for food, much less do so in a way that preserves the environment and resources for generations to come."[288]

Others insist that new crop varieties – including those developed through biotechnology and traditional breeding – will be critical for feeding hungry populations in Africa and Asia.[289] Genetic modification offers faster development than traditional breeding and the opportunity to enhance nutrients (e.g., vitamin A) through biofortification.[290] As a tool for agricultural improvement, "genetic technology, although by no means a panacea, facilitates breeding and widens the scope" of traditional

[284] N.V. Federoff et al., Radically Rethinking Agriculture for the 21st Century, 327 Sci. 833 (12 Feb. 2010).

[285] Id. at 833.

[286] Chicago Council, supra note 56, at 11 (defining sustainable intensification as agriculture that is "productive, sustainable, nutritious, and resilient to setbacks").

[287] Id. at 26. Private-sector biotechnology research is unlikely to develop crops that do not offer significant profit.

[288] Id. at 5.

[289] See Judith A. Chambers, et al., GM Agricultural Technologies for Africa: A State of Affairs (African Development Bank & IFPRI, 2014) (recognizing the potential of GM technology for Africa, but raising critical issues including capacity, regulatory policy, intellectual property rights, trade and markets, and environmental issues).

[290] Christopher J.M. Whitty et al., Africa and Asia need a rational debate on GM crops, 497 Nature 31, 32 (2 May 2013). See generally Hossein Azadi & Peter Ho, Genetically modified and organic crops in developing countries: A review of options for food security, 28 Biotechnology Advances 160, 166 (2010).

breeding."[291] Indeed, as scientists recently asserted, "[e]xcluding any technology that can help people to get the food and nutrition that they need should be done only for strong, rational and locally relevant reasons."[292]

As the discussion in this Chapter indicates, US science-based laws and regulations help to ensure the safety of new GM varieties for agriculture, the environment, and human health. Although GMOs have been embraced in the United States, many other nations accept GM crops reluctantly or not at all, and requirements for authorization vary significantly. Regulatory barriers and asynchronous approvals of GM varieties affect trade and the ability of producers and consumers to access GMOs and their products. Although GM crops offer important benefits and their products have been consumed for decades "without incident,"[293] controversy about these products is likely to continue. Nevertheless, the legal community may well agree with scientists who recommend the development of "forward-looking regulatory frameworks based on scientific evidence" that are less "complex, costly and time-intensive."[294] To eliminate hunger, these scientists insist, "we must scale up and further build on the innovative approaches already under development, and we must do so immediately."[295]

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[291] Sven Ove Hanson & Karin Joelsson, Crop Biotechnology for the Environment?, 26 J. Agric. Envtl Ethics 759, 767 (2013): "Therefore, today, the issue is no longer yes or no to crop biotechnology, but what direction it should take." Id.

[292] Whitty et al., supra note 290, at 33. See the recommendation of Federoff & Kershen, supra note 75, at 875:

> If modern science is to contribute to the agricultural productivity increases required in coming decades as the climate warms and the human population continues to grow, it is imperative to get beyond the cultural and political biases against molecular crop modification, acknowledge the safety record of GM crops, and ease the regulatory barriers to their development and deployment.

[293] Federoff et al., supra note 284, at 833. See also Alessandro Nicolia et al., An overview of the last 10 years of genetically engineered crop safety research, Critical Rev. in Biotec. (2013), DOI: 10.3109/07388551.2013.823595: "The scientific research conducted so far has not detected any significant hazards directly connected with the use of GE crops."

[294] Federoff et al., supra note 284, at 833. (recommending assessment of data on GM crop safety and reevaluation of the existing regulatory framework in the United States). See also EASAC, supra note 4, at 2 (2013): "The [European Union] regulatory framework must be reformulated appropriately to be science-based, transparent, proportionate and predictable, taking into account the extensive experience gained and good practice implemented worldwide." The EU chief scientist endorsed the conclusions of the EASAC report, a joint statement of EU scientific academies. EU chief scientist: 'It is unethical not to use GM technology,' EurActiv, 26 Sept. 2013, http://www.euractiv.com.

[295] Federoff et al., supra note 284, at 834.

Chapter 10
Country Report: Canada

Marie-Eve Arbour and Steven Hoeung

Genetically modified organisms are at the heart of the Canadian economy. Generally speaking, GMOs are perceived as foodstuffs capable of fostering trade rather than a threat to people's health. WTO litigation or the absence of EU-Style labeling suggest that GMO enjoy great support from the government and the population. Although some municipalities declare themselves GMO-free, "moratoria" or "thresholds" are extraneous to the Canadian GMO-legislation. In addition, private law reveals itself quite incapable of compensating damages sustained by GMO activity. In synthesis, Canada aligns itself to liberal attitudes to GMO farming.

Introduction

Crops lie at the very heart of Canada's economy. Wheat, corn, canola or soya have all found great conditions for growth within the vast territory of the country, mostly in the mid-west provinces' Great Plains (Manitoba, Saskatchewan and Alberta), but also in Quebec, Ontario and British Columbia. Fruits and vegetables –potatoes, cherries, peaches, apples, and berries – also form a significant part of these last provinces' economic landscape. Given the importance of agriculture in the development of the country, its federal structure apprehends it as one of the competences enumerated at the 1867 Constitution Act.[1] Legislative endeavours were also taken at

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[1] Art. 95, Constitution Act, 1867 (UK), 30 & 31 Vict, c 3, ss 91–92, reprinted in RSC 1985, App II, No 5 [1867 Constitutional Act].

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the federal level through other peripheral competences, such as interprovincial trade (labelling), criminal matters[2] (used to enact the general Food and Drugs Act[3] and derived regulations[4]), or health, a shared competence. This legislative action superposes itself to the exclusive provincial competence over private matters and civil rights,[5] which has a profound impact on foodstuff regulation (contract, torts, consumer protection, labelling, etc.).

This partaken legal framework underlies a regulation strategy through the creation, in 1997, of the federal Canadian Food Inspection Agency [CFIA].[6] Though in no way comparable to the Food and Drug Agency [FDA] or the European Food Safety Authority [EFSA], the CFIA enjoys, besides its regulatory mission, wide inspection powers over food facilities that may even end in compulsory recall orders.[7] The efficiency of these powers is nonetheless tributary of monetary resources and proper staffing that are allocated to such endeavor: they have, in recent years, suffered important cuts. In special circumstances, other authorities are involved in the regulation of GMOs, further puzzling the legal panorama.[8]

[2] Art. 91 (27), 1867 Constitution Act.

[3] Food and Drugs Act, RCS 1985, c F-27. See R v Wetmore, [1983] 2 S.C.R. 284 at 288–289, 2 DLR (4th) 577; Berryland Canning Co v Canada, [1974] 1 F.C. 91 at 7–8, 44 DLR (3d) 568: "The said legislation, with a view to a public purpose, is primarily designed to protect the health of Canadians by prohibiting the adulteration of foods and to suppress fraud in the distribution of food products. Hazards coming from drugs, cosmetics and devices, as therein defined, also fall within the scope of this legislation."

[4] Food and Drug Regulations (C.R.C., c. 870).

[5] This so, pursuant to art. 92 (13) of the Constitutional Act.

[6] Canadian Food Inspection Agency Act (S.C. 1997, c. 6). "WHEREAS the Government of Canada wishes to enhance the effectiveness and efficiency of federal inspection and related services for food and animal and plant health by consolidating them; WHEREAS the consolidation of those services under a single food inspection agency will contribute to consumer protection and facilitate a more uniform and consistent approach to safety and quality standards and risk-based inspection systems; WHEREAS the Government of Canada wishes to have that food inspection agency deliver those services in a cost effective manner; […]".

[7] See 19. (1) of the Canadian Food Inspection Agency Act: "Where the Minister believes on reasonable grounds that a product regulated under an Act or provision that the Agency enforces or administers by virtue of section 11 poses a risk to public, animal or plant health, the Minister may, by notice served on any person selling, marketing or distributing the product, order that the product be recalled or sent to a place designated by the Minister". A website is dedicated to these: see e.g. "Allergy Alert – Undeclared milk in certain Clic brand strawberry flavored marshmallow", oct. 26th, 2013, online at http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recall-warnings/complete-listing/2013-10-26/eng/1382809101752/1382809117917

[8] Such as Environment Canada (for microorganisms and GM animals); Fisheries and Oceans Canada (who will eventually set its own procedure for the dissemination of GM aquatic microorganisms, for now under the surveillance of Environment Canada).

General Information

Use, Public Opinion, Position of Government

Along with the United States and Argentina, Canada has taken the lead in the production and commercialization of genetically modified organisms[9] [GMO[10]]. As a major exporter, it has opposed the European Union [EU] upon the World Trade Organization [WTO] scene, advocating for the removal of obstacles to trade linked with the risk/benefice *ratio* that is carried on by national and supranational regulators. In line with Canada's current economic development strategy, the Government of Canada is, apparently, as much concerned by the disruption of trade as it is by the danger that GM foods pose to the health and safety of Canadian consumers. For example, promoting one of its most fruitful industry, the Government considers that grains and food products for animals and humans that contain 0.1 % or 0.2 % of GM product are not likely to compromise national health. As such, they will not be subjected to the regular surveillance of the Canadian Food Inspection Agency.[11] Contrasting the EU reality, such a keen attitude to GMO farming can probably be explained by the correlative lack of opposition from the civil society.

Among a very few, a public consultation was carried throughout Canada by the Government in 2012–2013 to discuss the prospect of importing "low level presence" (LLP) of genetically modified (GM) foods on a new level.[12] The objective of such consultation was to gather the outlooks of all Canadian citizens, both public

[9] At the national level, see e.g. Hategekimana and M. Beaulieu, "Genetically modified crops: Steady growth in Ontario and Quebec", 2002, in Vista on the Agri-Food Industry and the Farm Community [www.statcan.gc.ca/pub/21-004-x/21-004-x2002112-eng.pdf], which highlights that "[GM] soybeans and corn in Quebec and Ontario accounted for a large share of the total Canadian production. In 2001, 29 % of Canadian corn production was grown from modified corn seeds. Modified soybeans represented 24 % of Canadian soybean production" (at p. 2). At the provincial level, see e.g. Institut de la Statistique du Québec, *Superficie des* grandes cultures génétiquement modifiées, rendement à l'hectare et production, par région administrative, Québec, 2012, which shows that GM soya crops represent 59 % (165 000 ha) of soya crops; and GM maize represents 83 % of Quebec's production.

[10] Technically, "GMO" is defined by the Canadian General Standards Board's Organic Agriculture Standards (approved by the Standards Council of Canada) as follow: "All organisms, and products thereof, produced through techniques of genetic engineering and modification including, but not restricted to recombinant DNA, cell fusion, encapsulation, macro and micro injection, gene deletion or magnification, and other techniques for altering the genetic composition of living organisms in ways, or with results, that do not occur in nature through mating or through traditional breeding techniques such as conjugation, hybridization, or transduction".

[11] Government of Canada, Agriculture and Agri-Food Canada, Government of Canada Proposed Domestic Policy on the Management of Low-Level Presence of Genetically Modified Crops in Imports and its Associated Implementation Framework, 2012, retrieved from www5.agr.gc.ca/resources/prod/doc/pol/consult/llp/pol_llp_pfq_e.pdf

[12] Redfern Research, Policy Approaches for Managing Low-Level Presence of Genetically Modified Crops Imported into Canada – Report on Stakeholder Consultations, 2011 [http://www.cban.ca/content/download/1915/11400/file/LLP%20Consultations%20report.pdf] Following this consultation, a draft policy was published on the website of Agriculture and Agri-Food Canada to outline the current position of the Government of Canada.

and stakeholders, on this controversial subject. Some are strongly opposed to any potential barrier to trade, and others are concerned with the impact of tolerating even the slightest amount of GM in foodstuffs. Despite this difference, there is a common ground on several points. For instance, stakeholders do entertain the idea that the Government of Canada should prioritize international cooperation through the establishment of an LLP policy and a strong scientific basis for any new LLP policies before venturing into a more controversial territory. Conversely, there is also some opposition from part of the civil society, who vehemently reject any LLP policy that would tolerate the presence of measurable amounts of unauthorized GM crops in imports, regardless of any scientific findings conducted by foreign regulators. This said, different attitudes can be observed in some provinces whereby environment protection is a core value (e.g. Quebec or British-Columbia).[13] For example, a survey at the national level reveals that 74% of Quebec's population wants to know risk associated with GMOs.[14] At the same time, the majority of Canadians (87%) would not actually know what the acronym "GMO" means.[15] Whether there is a "Canadian consensus" over GMO farming remains an open question.

Food Safety: Definition, Political Concept

In 1996, 180 nations gathered at the Food and Agriculture Organization of the United Nations headquarter (FAO) to find a solution to the global hunger crisis. The conclusions of this meeting are summarized in two documents, the Rome Declaration on World Food Security and the World Food Summit Plan of Action, in which Canada has expressly endorsed the goal.[16] By acknowledging the priorities lay out

[13] See specifically Z. Komirenko, M. M. Veeman and J. R. Unterschultz, "Do Canadian Consumers Have Concerns about Genetically Modified Animal Feeds ?" (2010) 13 The Journal of Agrobiotechnology Management & Economics, p. 248–249, or The British Columbia Fruit Growers' Association, Survey Finds Risk of Consumer Backlash on GMOs, 2012 [www.bcfga.com/files/file/GMO%20Survey%20July%203,%202012.pdf] In response to the following question: "Are you in favour or the approval of this [genetically engineered] apple by Health Canada?" 69 % of respondents were not in favour.

[14] Léger & Léger, Sondage auprès des consommateurs quant à leurs perceptions à l'égard des OGM (Omnibus), May 2001, at p. 11, cited in Gouvernement du Québec, Contexte social, online at http://www.ogm.gouv.qc.ca/info_contexte.html

[15] La Pressse canadienne and Léger Marketing, Étude sur les perceptions des Canadiens à l'égard des Organismes Génétiquement Modifiés, 2001, at p. 2. cited in Gouvernement du Québec, Contexte social, supra. Cfr. Decima Research, Emerging Technologies Tracking Research, 2006, retrieved from http://www.ic.gc.ca/eic/site/icgc.nsf/vwapj/Decima-June2006_EN.pdf/$file/Decima-June2006_EN.pdf, whereby a report submitted to Industry Canada showed that "Canadians express reticence about the impact of some applications of technology over this period. Some examples include GM animals (where 58 % believe it will make life worse over the next 20 years), GM fish (54 %), and GM foods (50 %). These are all seen to have a more negative than positive effect" (pp. 3–4).

[16] See Food and Agriculture Organization of the United Nations. Rome Declaration on World Food Security and World Food Summit Plan of Action, 1998 [http://www.fao.org/docrep/003/w3613e/w3613e00.HTM].

in both documents; Canada has made the commitment to reform its domestic and foreign policies in order to reduce food insecurity by half no later than the year 2015.[17] From a political perspective, it was a significant step for Canada as prior to the 1996 meeting, the definition of food security had never been the object of serious reflection. The Canadian government endorsed the following definition as part of their international commitment: "Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life". According to G. Parent, this definition is sufficiently broad to address problems that are specific to economically developed countries, such as obesity, and, for our purpose, GM product's consumption.[18]

Food safety[19] is well alive in Canadian and provincial legislation, case-law and scholarship. Most provinces have adopted similar food safety technical regulations or more general laws[20] destined to create safety maxi-obligations in order to easily pinpoint liability ("an operator is responsible for ensuring that the food in his or her food establishment is safe for human consumption[21]") whilst prohibiting the sale of a contaminated foodstuff ("an operator must not sell or distribute to a person any item of food that is contaminated or otherwise unfit for human consumption"). As a political concept, food safety is widely used to design Canada's personality in the eyes of consumers. Recent scandals such as those involving packaged meat[22] and the cheese industry[23] have increased the need of stronger State intervention. In fact, the dynamism of the notion within these fields clearly contrasts with the

[17] Agriculture and Agri-Food Canada, Canada's Action Plan for Food Security, 1998 [http://www.agr.gc.ca/misb/fsec-seca/pdf/action_e.pdf].

[18] G. Parent, "Droit économique et sécurité alimentaire: un couple mal assorti?", (2012) 4 Rev. int. de droit écon., p. 15 (at p. 16).

[19] For the purpose of this Report, "food safety" and "food security" will be used indistinctly, following the FAO's will after the Summit held in Rome in 1996 (on the merging of these concepts, see G. Parent, ibid.).

[20] See e.g., in British Columbia, the Food Safety Act, SBC 2002, c 28.

[21] B-C. Food Safety Act, SBC 2002, c 28, art. 2.

[22] A national outbreak of listeriosis associated with cold cuts from a Maple Leaf Foods plant in Toronto, Canada, occurred in 2008. Out of the 57 confirmed cases, 22 people died after consuming the product. The plant responsible for spreading this disease has undergone intense sanitation under the inspection of Maple Leaf Foods' officials. On December 2008, four separate class-action lawsuits were settled after the company promised to compensate the victims for 27 millions dollars: see The Globe and Mail, "Listeria lawsuits against maple leaf settled for $27-million", Dec. 18, 2008 [www.theglobeandmail.com/news/national/listeria-lawsuits-against-maple-leaf-settled-for-27-million/article1067849/].

[23] In September 2008, the government of Quebec ordered the shutdown of several cheese manufacturers and the destruction of their products on sale in the wake of an outbreak of listeriosis. 28 people were infected with one deceased after consuming the commercialized cheese. The government was initially criticized for refusing to compensate the financial loss of cheese manufacturers, yet this situation was easily overcome based upon the increased turnover in the upcoming months. Cheeses made from raw milk are closely regulated by public agencies since the event. See Le Devoir, « Listériose–Québec pourrait aider l'industrie de fromage », Sept. 18, 2008, [http://www.ledevoir.com/politique/quebec/206306/listeriose-quebec-pourrait-aider-l-industrie-du-fromage].

absence of overarching legal principles from which it should derive (see section "Legal superstructure, right to food and the precautionary principle").

Within this context and despite the apparent centrality of health concerns, GMOs have been perceived as an occasion to foster trade and commerce. Cited surveys, WTO litigation and the absence of labeling EU-style indeed suggest that the GMO industry enjoy a massive support from the government and, overall, the population. As a result and probably more than other foodstuffs (e.g. raw meat and fish or non-pasteurized cheeses), GMOs are just part of Canadian's (agri)culture.

They are more fiercely contested whenever they may pose a threat to trade, as has experienced Monsanto's new product Roundup Ready Wheat [RRW] at the turn of the new millennium.[24] Fearing cross-contamination of traditional wheat crops –the predominant market in Canadian agriculture–, farmers of Saskatchewan and Manitoba, along with the Canadian Wheat Board, engaged into a duel with famous multinational and Health Canada. Specifically, they argued that inevitable contamination of most fields would impede farmers from guaranteeing their buyers (Japan, European countries, etc.) that Canadian wheat grain and flour are GMO-free, a contractual condition for exportation. According to Mauro, McLachlan and Van Acker: "[t]he primary benefits associated with RRW were associated with weed control, whereas risks emphasized the importance of market harm, corporate control, agronomic problems, and the likelihood of contamination. Overall, risks were ranked much higher than benefits, and the great majority of farmers were critical of RRW commercialization".[25] Likewise the canola industry, loss of confidence would materialize in an important decrease of wheat exportations, knowing that the segregation of crops is at best costly, or, at worst, illusory. Ultimately, farmers' pressure led Monsanto to withdraw its market authorization application in 2004.

Legal Superstructure, Right to Food and the Precautionary Principle

Within this context, it may not be surprising that there be no such right to food in Canada. Although the Canadian Charter of Rights and Freedom evokes rights such as dignity, life or one's security, they have never embraced, as such, any black letter or case-law created "right to food". The Constitution, hence, does not lay down any basis for such right, although Canada has indeed ratified, in 1966, the *International*

[24] On this issue, see I. J. Mauro, S.M. McLachlan & R. C. Van Acker, "Farmer knowledge and a priori risk analysis: pre-release evaluation of genetically modified Roundup Ready wheat across the Canadian prairies", (2009) 16 Environmental Science and Pollution Research, p. 689.

[25] I.J. Mauro, S. M. McLachlan & R. C. Van Acker, "Farmer knowledge and a priori risk analysis: pre-release evaluation of genetically modified Roundup Ready wheat across the Canadian prairies", (2009) 16 Environmental Science and Pollution Research, at p. 689. See also J. M. Marcoux and L. Létourneau, "A distorted regulatory landscape: Genetically modified wheat and the influcnece of non-safety issues in Canada", (2013) 40 Science and Public Policy, p. 514.

Covenant on Economic, Social and Cultural Rights.[26] In fact, a recent – quite astonishing, indeed – Report released by Special reporter of the United Nations Olivier de Schutter[27] has identified a "growing number of people across Canada unable to meet their basic food needs". He further highlighted that "[i]n 2007/2008, 7.7 % of households reported experiencing moderate or severe food insecurity, approximately 1.92 million people, aged 12 or older, lived in food insecure households and a staggering one in 10 families, with at least one child under the age of six, were food insecure[28]". Likewise, the Special reporter has shown deep concern over severe food insecurity affecting the aboriginal people living off-reserve (in particular, those living in the Northern Territories).

He concluded that the poor access to organic food, and the rising number of malnutrition cases are among the factors that need to be addressed at both the national and provincial level. Unfortunately, according to the report, Canada lacks a national right to food strategy to meet these challenges. Canada also heavily relies on an export food system that has gradually overshadowed the development of local food, making children vulnerable in "schools, undeserved urban and Northern remote communities.[29]" The GMO panacea, hence, has not solved all problems.

Nor is there any anchor to the precautionary principle, as, conversely, Canada has fiercely defended GMO products against the obstacles to importations that had been erected by the EU in the 1990s. By contrast, the scientific community itself has advocated for finer consideration given to the precautionary principle. Upon request from Health Canada, the CFIA and Environment Canada, a report on the future of food biotechnology signed by the Royal Society of Canada[30] recently stressed the need, preceding approval, for greater precaution and independent testing of GMO. The experts were of the opinion that increased use of transgenic products could pose an imminent threat to the health and security of Canadian consumers and, therefore, the activities of farmers ought to be closely regulated. In response to the formulated recommendations,[31] Health Canada acknowledged to "fully support a precautionary approach when reviewing products for human and environmental safety. The language of Principle 15 of the 1992 Rio Declaration on Environment and Development, and the approach that it represents are consistent with today's

[26] International Covenant on Economic, Social and Cultural Rights, 16 December 1966, 993 UNTS 3, 6 ILM 368 (entered into force 3 January 1976) available at: http://www.refworld.org/docid/3ae6b36c0.html [accessed 4 November 2013].

[27] United Nations, Human Rights Council, G. A., Report of the Special Rapporteur on the right to food, Olivier De Schutter, A/HRC/22/50/Add.1, 24 Dec. 2012 [www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/AHRC2250Add.1_English.PDF].

[28] Id., p. 4.

[29] Id., p. 9.

[30] Royal Society of Canada, Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada, 2001 [http://rsc-src.ca/sites/default/files/pdf/GMreportEN.pdf].

[31] Health Canada, In response to the Royal Society of Canada's Expert Panel Report titled: "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada, 2001 [http://www.hc-sc.gc.ca/sr-sr/alt_formats/hpfb-dgpsa/pdf/pubs/rsc_response-reponse_src-eng.pdf].

regulatory practices within the field of environmental protection in Canada". In particular, it recognized that substantial equivalence shall "not to be used as a decision threshold and GM-products should be subject to a rigorous scientific assessment of their potential for causing harm to the environment or to human health".

For the time being, recommendations do not seem to have been followed. Indeed, the political wind changed in Ottawa; since 2002, we rather witness a shift towards deregulation of food biotechnology in order to promote a freer market for GMOs.

Access to the Market

As a regulator, Health Canada is responsible, pursuant to the *Food and Drugs Act* and its derived Regulations, of increasing public health and food safety: "[t]hrough science-based regulation – one reads on its Website – guidelines and public health policy, as well as health-risk assessments concerning chemical, physical and microbiological contaminants, toxicants and allergens in the food supply, Health Canada works to protect the health and safety of Canadians". Central to the regulation strategy are pre-market evaluations destined to assess the safety and nutritional adequacy of novel foods, including biotechnologies.[32] Words such as "moratoria" or "thresholds" are extraneous to the field's vocabulary; indeed and in line with the policies set forth by the actual government, legal impediments to GMO farming are but a few.

Restriction of GMO, Safeguard Clauses, Subsidies and GMO-Free Zones

Apart from the risk assessment carried on by the Canadian regulator, there are no such legal restrictions to the dissemination of GMO on one's land. As farming practices remain linked to property (see the *Schmeiser* case, *infra*), any debate remains within the private sphere and does not, from a legal standpoint, trigger public interest legislation. Hence, whenever farming practices abide to provincial and federal agri-laws and regulations (zoning, etc.), no other impediment will restrict their property right to exploit their fields as they please, be it traditional or GMO. However, some voluntary actions were taken at a more local level. For example, some British-Columbia municipalities have passed resolutions declaring themselves GMO-free

[32] According to Health Canada, biotechnology is merely "an umbrella term that covers a broad spectrum of scientific tools and techniques, including genetic modification and genetic engineering". Semantically speaking, genetic modification refers as "[a]n organism, such as a plant, animal or bacterium, […] if its genetic material has been altered through any method, including conventional breeding. A "GMO" is a genetically modified organism", whilst "Genetically engineered" are those organisms "genetically modified using techniques that permit the direct transfer or removal of genes in that organism. Such techniques are also called recombinant DNA or rDNA techniques" (Health Canada website, id.).

territories.[33] It is our opinion that such endeavours seem political more than anything else, as they could probably be successfully challenged in courts. Indeed, the only impediment to GMO farming remains the absence of proper authorization by the Canadian regulator.

Admission of GMO: the Legal Requirements and Procedures

Admission of GMO in food production is regulated at the federal level by Health Canada and the CFIA. In this regard, the *Food and Drug Regulations* specifically addresses the sale of novel foods in Canada through a pre-market notification requirement[34] (see section "Annex I – risk assessment process – novel foods"). Based, tautologically, on scientific novelty,[35] this regulatory scheme focuses upon the effects rather than the causes: market approval will be necessary if the foodstuff carries some trait not previously found within the species, regardless of whether they be created through genetic engineering or more traditional breeding methods (e.g. selective breeding, cell fusion, mutation breeding). Otherwise, if the seed in not novel or is *substantially equivalent* to a previously authorized one, it will be exempted from such approval process. The market authorization procedure follows a two-steps process, and encourages proponents to engage in a pre-submission consultation with the Novel Foods Section. These steps are the following.

Pre-market Notification

Whenever a product proponent gathers sufficient information on the safety of a GM product, submission may be made to Health Canada's Novel Foods Section. The relevant scientific criteria are described quite in details in *Health Canada's Guidelines for the Safety Assessment of Novel Foods*. As in other fields such as pharmaceuticals, the experimentation process is carried on by the proponent itself, as the government, likewise in most other countries, does not substitute itself to

[33] See http://www.cban.ca/Resources/Topics/GE-Free-Zones

[34] Division 28 of Part B of the Food and Drugs Regulations.

[35] Pursuant to art. B.28.001 of the Food and Drugs Regulations, novelty is defined as "(a) a substance, including a microorganism, that does not have a history of safe use as a food; (b) a food that has been manufactured, prepared, preserved or packaged by a process that (i) has not been previously applied to that food, and (ii) causes the food to undergo a major change; and (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism, (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.The centrality of the scientific expertises is further explored by Jean-Michel Marcoux and Lyne Létourneau, "A distorted regulatory landscape: Genetically modified wheat and the influence of non safety issues in Canada", (2013) 40 Science and Public Policy, p. 514.

private laboratories or universities, though it may have a close look at the experimented confined fields. Whenever carried on in Canada, pre-market protocols may be submitted to prior authorization by universities' ethics committees or other governmental bodies (such as Ministry of the Environment). Scientific assessment of pre-market notification documentation by the Canadian regulator is, therefore, a "second reading" of pre-existing protocols, experiments and drawn conclusions by the proponent itself (or its contractual partners).

Scientific Assessment

Health Canada's scientific team (with expertise in molecular biology, toxicology, chemistry, nutritional sciences and microbiology) will assess the following variables, retrieved from Health Canada's website[36]:

- development of the modified organism, including the molecular biological data that characterizes the genetic change;
- composition of and nutritional information about the GM food compared to a non-modified counterpart food;
- the potential for production of new toxins in the food;
- the potential for causing allergic reactions;
- microbiological and chemical safety of the food;
- the potential for any unintended or secondary effects;
- key nutrients and toxicants; and,
- major constituents (for example, fats, proteins, carbohydrates) and minor constituents (for example, minerals and vitamins)

During the assessment process, regulators may ask the proponent further documentation. Risk/benefit assessment will only be carried on whenever all the requested information is provided by the proponent (and is deemed scientifically sound). Upon completion of the risk assessment, the evaluators will summarize their findings and formulate proper recommendations, untitled *Health Canada Food Rulings Proposal*. Decision to approve the product will materialize into a *Letter of no objection*, which shall specify the product's intended uses, along with any application restrictions or requirements. Finally, Health Canada will post a summary of the decision on its website (the *Novel Foods and Ingredients page*).[37] Likewise the pharmaceutical field, most of the information regarding the assessment process is confidential, as furnished data *ipso facto* underlies the existence of patent.

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[36] http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg_gen_mod-eng.php

[37] See for example CFIA, "DD2005-53: Determination of the Safety of Monsanto Canada Inc.'s Roundup Ready® Alfalfa (Medicago sativa L.) Events J101 and J163", http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd2005-53/eng/1311630531051/1311631992012

Implementation and Enforcement/Compliance?

Compliance is compulsory, as a proponent that does not hold a proper authorization simply does not have access to the Canadian market. Strategically, however, it is difficult to imagine a company who would deliberately ignore the governmental authorization process, in a world where the economic operators are so very few. To the contrary, Health Canada rather works in close collaboration with the GM industry in the testing and development of new products.

Labelling Regime

Anecdotal evidence seems to speak for itself. "WARNING: This product may contain genetically modified organisms (GMO) which has not been adequately tested and could be dangerous to your health and environment": this is not a compulsory label affixed on some products, but a criminal offense perpetrated be two students who were arrested for having labelled several products in a grocery store.[38] Whilst prosecuted on the charge of mischief,[39] they alleged that they lawfully defended themselves by reason of necessity and/or civil disobedience.[40] Rejecting the accused's assumptions,[41] the Court found them guilty of mischief on the ground that the damage caused to the supermarket was permanent, as removing the stickers would ruin the packages. Once the merchandise had been labelled, hence, it could not be sold. The condemnation was upheld by the Court of appeal.

GMO labelling, in fact, remains voluntary in Canada; which amounts to stating that there is none. Indeed and pursuant to the *Food and Drugs Act*, Health Canada and the CFIA may impose labelling whenever the product poses a risk for human health or comprises an allergenic component. As GMO foodstuff have never been the target of such interventions, it is to believe that they are not held by the government to pose a threat for people's health. In fact, GMOs are part of Canadian menus, to an extent unknown to consumers.

[38] R. c. Petit, 2001 CanLII 27032 (QC CM) [http://canlii.ca/t/1t8vf].

[39] Pursuant to art. 430 of the Criminal Code (a federal law).

[40] Id., art. 429(2).

[41] Civil disobedience can only be invoked to justify a damage done to a public good with the objective to revolt against an oppressive law. These conditions have not been met. The defence of necessity is also rejected, because the defendants did not demonstrate the imminent danger surrounding the use of GMO.

Labelling/ Labels "Food Free of GMO" or on the Use of GMO for Organic Food?

The only way of avoiding them is turning to the organic market. Conversely, labelling affects GMO-free foodstuff (organic). To say things in J. Glenn's words: "The only food clearly free of GMOs is organic, and this places the burden of segregation, and traceability, and labelling that goes with it, on organic rather than GM or conventional producers[42]". Just as GM farming had become the traditional way to agriculture –organic methods remaining marginal– importance will be herewith given to organic food labelling. Since 2009, the CFIA has put an end to the variety of schemes (voluntary and compulsory) that had been adopted throughout Canada until then.[43] Proposing a solution to the interprovincial trade of organic products, *Organic Products Regulations* were adopted in 2009.[44] These regulations are enforced alongside the Canadian Organic Standards, which defines the practices to be followed in order for a product to be labelled organic. Here, private governance plays an important role as the Regulations lean on standards in order to set normative boundaries to organic farming. For example, the Regulations provide that "[…] the percentage of organic products contained in a multi-ingredient product shall be determined in accordance with CAN/CGSB 32.310[45]". This last standard is very technical in nature and is posted on one the governments' website.[46]

Certification may be obtained by a third-party Certification Body accredited by the CFIA – in no way restricted to Canadian entities, embracing US, EU and other bodies[47] – whenever a product is considered organic by the 2009 Regulations: "(1) A person who wishes to package and label an organic product shall apply to a certification body […] for certification that the packaging and labelling are done in

[42] See specifically J. M. Glenn, "Damage Caused by GMOs under Canadian Law", in Bernhard A. Koch (ed.,), Damage Caused by Genetically Modified Organisms – Comparative Survey of Redress Options for Harm to Persons, Property or the Environment, De Gruyter, at p. 663 [Glenn, "Damage"].

[43] For further description of this context, see Sophie Lavallée and Geneviève Parent, « Qu'y a-t-il derrière l'étiquette "bio" ? Une étude de l'encadrement juridique de l'agriculture et de la certification biologiques au Canada », (2005) 50 McGill L.J. 89. Provincial laws could be adopted to regulate intraprovincial trade : there nonetheless seems to be a natural alignment towards the federal model, compulsory whenever there is "exportation" of an organic product in another province (interprovincial trade).

[44] SOR/2009-176 [2009 Regulations]. These regulations were adopted pursuant to the Canada Agricultural Products Act, RSC 1985, c 20 (4th Supp) [http://canlii.ca/t/hxzr].

[45] Id., at art. 11.

[46] Public Works and Government Services Canada, Permitted Substances List, CAN/CGSB 32.310 [http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/permises-permitted-eng.html].

[47] The list is available at CFIA, http://www.inspection.gc.ca/food/organic-products/certification-and-verification/certification-bodies/eng/1327860541218/1327860730201

accordance to the requirements set out in CAN/CGSB 32.310 […][48]". In light of this regime, only products properly certified containing more than 95 % of organic content may be labelled "Organic[49]" or bear the regime's logo (this is to say that a "100 % organic" claim is illegal!). Besides, certified multi-ingredient products having a 70–95% organic content may affix the following statement: "contains x% organic ingredients". These products may not use the organic logo and/or the claim "Organic". Finally, multi-ingredients products having content less than 70 % "organic" may only refer that quality within the product's ingredient list. Such products need not be certified and shall not use the logo, albeit the organic ingredient must have been certified prior to its incorporation into the final foodstuff.

The Canada Organic Regime is compulsory for whoever intend to label organic food as such. Putting an end to the chaotic multiplication of private and provincial endeavours, will it increase consumer confidence in organic products? Only time will tell.

Liability

Ever since public law surrounding GMO regulation presents, compared to other legal systems, a minimalist aesthetic, liability is expected to play an important role within the Canadian legal panorama, although there is no specific liability scheme in this regard.[50] As a preliminary observation, one must remember that although Canada is mostly a common law tradition country, Quebec's mixed system introduces, since 1774, the civil law tradition within the Province, whereby a Civil Code lastly entered into force in 1994 (translated into English). Addressing liability stemming from GMOs therefore means apprehending contractual warranties, *contrats*, negligence, *faute*,[51] *garantie de qualité*, nuisances, trespass, *responsabilité du fait*

[48] The article goes on stating that "(2) The application shall contain (a) the name of the organic product packaged and labelled; (b) a statement naming the substances used in the packaging and labelling of the organic product and describing the manner in which those substances are used; and (c) a report setting out in detail the packaging and labelling methods used and the control mechanisms in place to ensure that those methods comply at all times with the requirements set out in CAN/CGSB 32.310".

[49] 2009 Regulations, art. 24(1). "Organically grown", "organically raised", "organically produced" or similar expressions are acceptable.

[50] See Glenn, "Damage", at p. 663.

[51] Article 1457 C.c. reads: "Every person has a duty to abide by the rules of conduct which lie upon him, according to the circumstances, usage or law, so as not to cause injury to another.

Where he is endowed with reason and fails in this duty, he is responsible for any injury he causes to another person by such fault and is liable to reparation for the injury, whether it be bodily, moral or material in nature.

He is also liable, in certain cases, to reparation for injury caused to another by the act or fault of another person or by the act of things in his custody".

des biens, *troubles de voisinages*[52] or the *Rylands vs. Fletcher* doctrine (accepted in common law provinces), all more or less reconfigured by federal or provincial statutory laws.[53] Despite the richness of these liability basis, case law remains scant, though interesting.

Legal Nature of Liability Law Governing Genetic Technology and Conditions for Liability (Such as Legal Damage, Causality, Illegality, Fault)

Intuitively (if not logically), wandering gene may suggest that the owner of a contaminated crop –especially if organic– sough compensation for the sustained damages. Oddly enough, Canadian case-law is rather marked by the very opposite situation, as the Supreme Court had to decide a case anchored into the breach of a patent introduced by plaintiff Monsanto, after wandering genes contaminated an adjacent field owned by the defendant Schmeiser, a Saskatchewan canola farmer.[54] It is not our purpose to enter deeply into the heart of the complex matter. However, reading the case through the lenses of socioeconomic considerations may highlight some features of Canadian law, as, wrote J. Glenn, "[t]he biotechnology companies attempt to place the responsibility on the farmers whose crops have been contaminated, with a patent infringement suit as their ultimate weapon". After litigation duly proceeded –Schmeiser had refused any settlement– Monsanto won throughout the trial court, the Court of appeal, and, ultimately, the Supreme Court. For Schmeiser, the only victory consisted in the publicity that surrounded the case: from a public relation angle, one may wonder if Monsanto's strategy was fortunate.

To begin with, Schmeiser accidentally found, indeed, Roundup Ready canola plants in his fields. Seemingly glad with such discovery, at harvest time he stored the GM seeds separately from the rest of its crop, and seeded, *the following year*, around 4 km^2 of canola. The breach then consisted of not having paid the annual licence fee associated with the use of the GM patented seeds in light of the *Technology Use Agreement* that ordinarily binds Monsanto with its contractual partners (buying farmers). The document clearly stipulates that buying farmers may not, among other things, save seed for replanting or inventory, therefore shifting the case's center of gravity from said "farming rights" onto intellectual property law.

A divided Court (5/4) held that "[…] a farmer whose field contains seed or plants originating from seed spilled into them, or blown as seed, in swaths from a neighbour's land or even growing from germination by pollen carried into his field from

[52] Article 976 C.c. reads: "Neighbours shall suffer the normal neighbourhood annoyances that are not beyond the limit of tolerance they owe each other, according to the nature or location of their land or local custom".

[53] See generally J. M. Glenn, "Footlose: Civil responsibility for GMO gene wandering in Canada", (2003–2004) 43 Washburn Law Journal, p. 547 [Glenn, "Footlose"].

[54] Monsanto Canada Inc. v. Schmeiser [2004] 1 S.C.R. 902 [Schmeiser].

elsewhere by insects, birds, or by the wind, *may own the seed or plants on his land even if he did not set about to plant them. He does not, however, own the right to the use of the patented gene*, or of the seed or plant containing the patented gene or cell[55]". M. Schmeiser had unlawfully "used" the invention, therefore infringing art. 42 of the *Patent Act*, a federal law. Despite such conclusion, plaintiff Monsanto's victory remained partial, as no economic damages were granted as Schmeiser's modest gains (less than 20 000$) were not attributable to the patented seed.

Being the span of the Schmeiser case much narrower than it may appear,[56] the question of liability for accidental contaminations' wholly remains.[57] As J. Glenn observed, an action in nuisance (that is, "an unreasonable interference with the use of enjoyment of land, causing either physical damage to the use or enjoyment of land, causing either physical damage to the land of injury to the health, comfort, or convenience of the occupier[58]") raises, apart from causation, two uncertainties. Is the action of a private nature or a public one[59]? What is the very nature of the alleged damages[60]? Given these difficulties, statutory, environmentally-anchored legal basis may be more appropriate than traditionnal legal tools. As J. Glenn suggests, contaminated crops' owners may better seek liability deriving from the breach of a statutory duty pursuant to provincial legislation: "[i]n Saskatchewan – for example – section 15 of the *Environmental Management and Protection Act*[61] guarantees to "any person" a right to compensation from "the person responsible for a discharge" for loss or damage incurred as a result of "the discharge of a substance" into the environment[62]". In addition, the *Environment Assessment Act*[63] prohibits any "development" that does not detain a Ministry approval in light of the same Act, leaving the door open to producer's liability.

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[55] Schmeiser. The dissenting bench rather held that "the plant cell claim cannot extend past the point where the genetically modified cell begins to multiply and differentiate into plant tissues, at which point the claim would be for every cell in the plant" (par. 138, per J. Arbour).

[56] Probably anticipating polemics, the Supreme Court itself had narrowed down the scope of the case: "[…] we emphasize from the outset that we are not concerned here with the innocent discovery by farmers of "blow-by" patented plants on their land or in their cultivated fields. Nor are we concerned with the scope of the respondents' patent or the wisdom and social utility of the genetic modification of genes and cells — a practice authorized by Parliament under the Patent Act and its regulations" (at para. 2, J. McLachlan and Fish).

[57] In our opinion, accidental contamination is not anything resembling the "use" of the invention: see Pfizer Corp. v. Ministry of Health, [1965] A.C. 512 (H.L.), whereby Lord Wilberforce observed that "if it can positively be proved that the possession was innocent of any actual use or intention to use, the defendant will not be held to have infringed" (p. 572) (cited in Schmeiser, at para. 55, J. McLachlan and Fish).

[58] J. M. Glenn, "Footlose", supra, at p. 554.

[59] Id., at p. 554.

[60] Id., at p. 555.

[61] Environmental Management and Protection Act, S.S.198384, c. E-10.2 (at art. 15) [EMPA].

[62] J. M. Glenn, "Footlose", supra, at p. 558.

[63] EMPA.

From a procedural (and substantial) standpoint, though, seeking compensation for alleged GMO contamination encounters obstacles of another nature, well demonstrated by case *Hoffman v. Monsanto Canada Inc.*,[64] decided within the context of a class-action certification request presented by the a group of Saskatchewan organic farmers.[65] The Court of appeal synthesizes the statement of claim, whilst plaintiffs "[…] allege[d] that the appellants and other organic grain farmers suffered financial losses as a result of the introduction and commercial use of Roundup Ready and Liberty Link canola. More particularly, [they] allege[d] that these strains of [GM] canola, which are open-pollinating, inevitably find their way onto their fields, thus preventing them from producing and marketing organically grown canola, and putting them to extra expense in producing other organically grown crops". The farmers invocated negligence, nuisance, trespass and the statutory tort of "discharging a pollutant" into the environment[66] to support their action.

The trial Court[67] saw a *prima facie* cause of action in statutory torts. However, it appeared much more prudent as to the existence of a duty of care underlying negligence, evoking US-style pre-emption arguments that shrink the magnitude of private remedies whenever a product is approved by a regulator. In the trial Court's (famous) words:

> […] there are policy considerations that […] would in my view bar or limit the imposition of the duty of care alleged on the defendants in the circumstances of this case. First, as the plaintiffs clearly plead […], both defendants received approval of the federal government for the unconfined release of their GM canola varieties prior to their release. *The imposition by the courts of a duty of care not to release these substances into the environment would therefore appear to be in conflict with express governmental policy.*[68]

This reasoning seems to suggest that the market authorization is the sole regulation strategy, as it lies in the premise that no harm shall ever result of serious risk/benefice analysis carried on by the government.[69] In other words: public law subsumes private remedies. And if any market failure ever crystallized – may we infer – it is a negative externality that the organic farmers must, in the end, bear. More generally, this conclusion seems at odds with quite recent case-law addressing the boundaries of a statutory authorization defense that suffers visible erosion. Except in exceptional cases, indeed, Canadian common law has never really abided to the

[64] Hoffman v. Monsanto Canada Inc., 283 DLR (4th) 190; [2007] 6 WWR 387; 293 Sask R 89, 2007 SKCA 47 (CanLII) (leave to appeal to SCC refused) [http://canlii.ca/t/1rg03] [Hoffman].

[65] These parties were in fact « shadow plaintiffs », as the action was throughout driven by the Saskatchewan Organic Directorate-Organic Agriculture Protection Fund, who was eagerly in search of a cause of action.

[66] Environmental Management and Protection Act, S.S.1983–84, c. E-10.2.

[67] Hoffman v. Monsanto Canada Inc., 2005 SKQB 225 (CanLII), http://canlii.ca/t/1kwr2 [Hoffman I].

[68] Queen's Bench for Saskatchewan, at par. 71, per J. Smtih [emphasis added]. The Court of appeal approved the underlying logic (see par. 59).

[69] See J. M. Glenn, "Damages", supra, at p. 688.

pre-emption paradigm, rather apprehending public law (prevention) and liability (compensation) as being intertwined.

From a procedural standpoint, besides, the trial Court could not find the necessary premises underlying a class-action: "[b]oth principles, that the class definition must bear a rational relationship to the cause of action and the proposed common issues (and therefore must not be unreasonably over-inclusive or under-inclusive), and that the representative plaintiffs must *establish an evidentiary basis* to permit the factual conclusion that such a class exists[70]". It saw no rational connection between the plaintiffs, the causes of action, or the raised common issues. Hence, certification was denied.

What, then is left for potential plaintiffs? Other causes of action that break the narrow scheme of the law of obligations, entering public interest torts or State liability. The former possibility is merely theoretical, as products approval usually falls within the discretionary powers that are akin to the political sphere rather than the operational one.[71] Unless the plaintiffs manage to show gross negligence or bad faith in occasion of the risk/benefice exercise, no liability will arise, as the regulator has no duty of care toward single individuals. It is immune from liability. As to public interest tort lead by environmental of consumers' associations, they may, too, encounter difficulties finding a cause of action as the federal evaluation process invites them, through a Website, to formulate comments prior to the risk/benefice assessment process. To what extent are non-scientific arguments taken into consideration? The question remains without any answer.

Finally, some causes of action may theoretically arise from an "unnatural use of land" as set out in *Rylands v. Fletcher.*[72] However and apart from the hypothesis of a negligent spreading of herbicides or GMO seeds in an adjacent field (in which case the "GM factor" would be merely incidental), *Schmeiser*-inspired farmer-to-farmer actions seem to be destined to a doom fate, at least in common law. Product liability may offer some anchor for compensation if bodily injuries were ever documented, at least in Quebec.

Product Liability

Canadian common law provinces have never been very keen on product liability laws, though some consumer laws may sooth buyers' pain in seeking compensation induced by defective products. Apart from the traditional *vice caché* action,[73] true

[70] Hoffman I, at par. 208 [emphasis in original text].

[71] Cfr. J. M. Glenn, "Damages", supra, at p. 668, more nuanced as she notes that some feature of the Canadian approval system (such as its lack of transparency, poor post-market surveillance) may well be more similar to a regulation failures raising "operational liability".

[72] See Glenn, "Footlose", supra, at p. 557.

[73] According to art. 1726, al. 1 of the Civil code, "[t]he seller is bound to warrant the buyer that the property and its accessories are, at the time of the sale, free of latent defects which render it unfit

US-1985/374/CEE product liability style is especially relevant in the Province of Quebec, on which we shall focus our attention.

The reform of the Civil Code in 1994 provided the occasion to add a basis to the pre-existing contractual latent defects: that is, extracontractual product liability. Article 1468 and 1469 C.c.Q. provide for a new, special liability regime for third parties.[74] The first provision reads: "The manufacturer of a movable property is liable to reparation for injury caused to *a third person by reason of a safety defect in the thing*, even if it is incorporated with or placed in an immovable for the service or operation of the immovable. The same rule *applies to a person who distributes the thing* under his name or as his own and to any supplier of the thing, whether a wholesaler or a retailer and whether or not he imported the thing". As to the second, it creates a threefold ——American inspired—— definition of defectiveness in these words: "A thing has a safety defect where, having regard to all the circumstances, *it does not afford the safety which a person is entitled to expect*, particularly by reason of a defect in the design or manufacture of the thing, poor preservation or presentation of the thing, or the lack of sufficient indications as to the risks and dangers it involves as to safety precautions". The consumer oriented criterion seems to set the premises of a successful action.

This safety obligation of which the producer is ultimately debtor is counterbalanced by the existence –hardly ever pleaded– of disturbing development risk defence that is provided for by article 1473 C.c.Q.[75] Likewise the drug litigation context, many uncertainties remain as to the magnitude of such defence to hypothetical GM-caused damaged. Could the OGM invoke, with success, the defense? Here, the "knowledge" variable is swayed in various directions. Firstly, because experiments and trials are protected –as anticipated– by patents and industry generated R&D, rendering discovery difficult; secondly, because dissent in OGM risk-related research[76] is being marginalized, questioning its ability to ever consti-

for the use for which it was intended or which so diminish its usefulness that the buyer would not have bought it or paid so high a price if he had been aware of them". The provision may be of relevant, but the Consumer Act provides for greater protection (see infra, this section "Product liability").

[74] Note that the introduction of the impossilité de cumul between contractual and extracontractual rules has enhanced the disparity problem existing between "contractual victims" and extracontractual ones.

[75] EU inspired, it states: "The manufacturer, distributor or supplier of a movable property is not liable to reparation for injury caused by a safety defect in the property if he proves that the victim knew or could have known of the defect, or could have foreseen the injury.
Nor is he liable to reparation if he proves that, according to the state of knowledge at the time that he manufactured, distributed or supplied the property, the existence of the defect could not have been known, and that he was not neglectful of his duty to provide information when he became aware of the defect".

[76] See e.g. Gilles-Éric Séralini et al., "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize", (2012) 50 Food and Chemical Toxicology, p. 4221, who demonstrated a risk for animal health, as "[t]he results […] demonstrate that lower levels of complete agricultural glyphosate herbicide formulations, at concentrations well below officially set safety limits, induce severe hormone-dependent mammary, hepatic and kidney disturbances.

tute good science, hence "knowledge"; and finally, since the extent of "traces" of knowledge remain foggy, raising doubts as to what variables and elements should have justified further research.[77]

Fortunately enough, Quebec's legal system has antibodies against these never ending questions, as the Consumer Protection Act does not envision the development risk defence as an exoneration cause. Relevant for the compensation of personal injury damages, it provides: "[a] consumer who has entered into a contract with a merchant is entitled to exercise directly against the merchant or the manufacturer *a recourse based on a latent defect in the goods forming the object of the contract*, unless the consumer could have discovered the defect by an ordinary examination[78]". Defect encompasses information failures as well, since "[t]he same rule applies where there is a *lack of instructions* necessary for the protection of the user against a risk or danger of which he would otherwise be unaware […]". Despite the *Hoffman*-like procedural obstacles and though proof of the defect is closer to the *vice-caché* stream of argument than the consumer expectation test set forth by the safety obligation, the contours of a class-action seem to be visible under this unique statutory provisions in Canada's legal picture.

In the absence of a special liability regime designed by other legislators, it appears extremely difficult to hold the State, the GM industry, or neighboring farmers for damages sustained by OGMs. Despite the expression of some wishes into such direction, no political will has arisen in this regard.

Summary and Conclusion

As briefly seen in this Report, Canada's liberal attitude towards the commercialization of GMO reflects upon most legal institutions: be it intellectual property, property law, torts or civil liability. The contrast with other legal systems such as that of the EU, for example, is obvious; as the legislator seems to have left to Courts the delicate task of striking a balance between stakeholder's rights and obligations. Vice-versa, Courts show resentfulness in applying traditional institutions to such a novel commercial activity, implicitly suggesting that the legislator must remain at the heart of regulation choices whilst designing *ad hoc* solutions and remedies. In the meantime, this Ping-Pong game abandons non-GMO farming practices to themselves, although Canada boasts itself of being an important player on the international scene. To sum up things with De Beer: "[w]hen the results of the decisions in

Similarly, disruption of biosynthetic pathways that may result from overexpression of the EPSPS transgene in the GM NK603 maize can give rise to comparable pathologies that may be linked to abnormal or unbalanced phenolic acids metabolites, or related compounds". Following a known controversy, the article was removed from the scientific periodical.

[77] See M.-E. Arbour, "Portrait of Risk Development as A Young Defence", (2014) 59 Revue de droit de McGill, p.1.

[78] Art. 53, par. 1, Consumer Protection Act.

Schmeiser and *Hoffman* are juxtaposed, a serious problem becomes apparent. Entities that patent biotechnological innovations have all of the rights associated with property ownership, yet have been relieved of the responsibilities traditionally imposed upon property owners[79]".

Annex I – Risk Assessment Process – Novel Foods

Food and Drug Regulations – Division 28 ("Novel Foods")

Interpretation

B.28.001. The definitions in this section apply in this Division.

"genetically modify"

"genetically modify" means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation. (modifier génétiquement)

"major change"

"major change" means, in respect of a food, a change in the food that, based on the manufacturer's experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to

(a) the composition, structure or nutritional quality of the food or its generally recognized physiological effects;
(b) the manner in which the food is metabolized in the body; or
(c) the microbiological safety, the chemical safety or the safe use of the food. (changement majeur)

"novel food"

"novel food" means

(a) a substance, including a microorganism, that does not have a history of safe use as a food;
(b) a food that has been manufactured, prepared, preserved or packaged by a process that

    (i) has not been previously applied to that food, and
    (ii) causes the food to undergo a major change; and

[79] J. De Beer, "The Rights and Responsibilities of Biotech Patent Owners", (2007) 40 University of British Columbia Law Review, p. X. See similarly K. Black and J. Wishart, "Containing the GMO Genie: Cattle Trespass and the Rights and Responsibilities of Biotechnology Owners", (2008) 46 *Osgoode Hall Law Journal*, p. X.

(c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that

(i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
(ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
(iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism. (aliment nouveau)

Pre-market notification

B.28.002

(1) No person shall sell or advertise for sale a novel food unless the manufacturer or importer of the novel food

(a) has notified the Director in writing of their intention to sell or advertise for sale the novel food; and
(b) has received a written notice from the Director under paragraph B.28.003(1)(*a*) or subsection B.28.003(2).

(2) A notification referred to in paragraph (1)(*a*) shall be signed by the manufacturer or importer, or a person authorized to sign on behalf of the manufacturer or importer, and shall include the following information:

(a) the common name under which the novel food will be sold;
(b) the name and address of the principal place of business of the manufacturer and, if the address is outside Canada, the name and address of the principal place of business of the importer;
(c) a description of the novel food, together with

(i) information respecting its development,
(ii) details of the method by which it is manufactured, prepared, preserved, packaged and stored,
(iii) details of the major change, if any,
(iv) information respecting its intended use and directions for its preparation,
(v) information respecting its history of use as a food in a country other than Canada, if applicable, and
(vi) information relied on to establish that the novel food is safe for consumption;

(d) information respecting the estimated levels of consumption by consumers of the novel food;
(e) the text of all labels to be used in connection with the novel food; and

(f) the name and title of the person who signed the notification and the date of signing.

B.28.003

(1) Within 45 days after receiving a notification referred to in paragraph B.28.002(1)(*a*), the Director shall review the information included in the notification and

(a) if the information establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient; or

(b) if additional information of a scientific nature is necessary in order to assess the safety of the novel food, request in writing that the manufacturer or importer submit that information.

(2) Within 90 days after receiving the additional information requested under paragraph (1)(*b*) the Director shall assess it and, if it establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient.

Chapter 11
Report on Section II.D "Policies and Regulations in Mexico with Regard to Genetic Technology and Food Security": Country Report: Mexico

Claudia Colmenarez Ortiz and Sol Ortiz García

In 1988 the first application for field trials of a GMO was formally received in Mexico. Since then a Biosafety law, few bylaws and national official standards were enacted in order to regulate the safe use of GMOs and to evaluate, control and avoid adverse effects to human health and the environment. The Law on Biosafety of Genetically Modified Organisms was enacted in 2005 in order to comply with international obligations derived from the Cartagena Protocol on Biosafety signed by Mexico in 2000. This law established a biosafety legal framework to regulate the use of GMOs, protect biodiversity, and promote the conservation of organisms which Mexico is center of origin and center of genetic diversity. Since then, 561 permits for the release of GMOs into the environment have been granted between 2005 and 2014. This report gives and overview of the country's approach to the use of GMOs, the current status of the biosafety legislation in Mexico and the development of policies and regulations since the first introduction of GM crops in the country.

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General Information

Research and Use of GMOs in Agricultural Production

Genetically modified organisms were formally used in Mexican fields for the first time in 1988. In this year, the first application for field trial release of insect resistant Bt tomato was presented at the General Directorate of Plant Sanitation (DGSV) at the Secretariat of Agriculture.

In 1990, the National Committee of Agricultural Biosafety (CNBA) was created as an advisory technical group supporting the DGSV in the assessment of applications for environmental release of genetically modified crops and for advising on regulations and policies on the topic.

A significant development on the legal framework in Mexico occurred throughout the decade of the 1990s. In 1991, the new Seeds Production Certification and Trade Law[1] regulated official research for the production and benefits of improved seeds and its certification. In addition, in 1994 the Federal Plant Health Law[2] included for the first time in Mexico the definition of transgenic material. Last but not least, a very significant step in the biosafety legal framework was the issue of the Mexican Official Standard NOM-056-FITO-1995,[3] which was the first legal instrument that regulated transgenic crops and established the phytosanitary requirements for field tests of GMO's. This Mexican Official Standard was implemented by the DGSV.

After the entry in to force of the North America Free Trade Agreement (NAFTA)[4] in 1994, maize exports from the United States increased in the following years in Mexico, including genetically modified maize starting with its commercial approval in 1996. In 1999 the Mexican government started a *de facto moratorium* for environmental release, including commercial planting of GM maize, but imports for processing and human consumption continued.[5] A year later, in 2000 the Mexican Government signed the Cartagena Protocol on Biosafety, adopting the precautionary

[1] Ley sobre Producción, Certificación y Comercio de Semillas published in D.O.F. in July 15, 1991 abrogated from August 14, 2007 repealed by decree published in D.O.F 15-06-2007. The Ley Federal sobre Producción, Certificación y Comercio de Semillas, published in D.O.F. in June 15, 2007. This law replaced the first Seeds Law, GMO's and all related activities where regulated by the Law on Biosafety of Genetically Modified Organisms published in 2005.

[2] Ley Federal de Sanidad Vegetal published in D.O.F. in January 5, 1994 last amended and published in D.O.F on November 16, 2011.

[3] NORMA Oficial Mexicana NOM-056-FITO-1995, Por la que se establecen los requisitos fitosanitarios para la movilización nacional, importación y establecimiento de pruebas de campo de organismos manipulados mediante la aplicación de ingeniería genética published in D.O.F. on July 11, 1996. This law was cancelled on October 13, 2006 D.O.F.

[4] North America Free Trade Agreement 32 I.L.M. 289 and 605 (1993).

[5] González Aguirre, R.L, Aguilar Muñoz, E.J., 2006. Bioseguridad y Actores sociales. In Presentation at the 2006 Latin American Studies Association Conference, San Juan, Puerto Rico quoted in Mercer, K.L., Wainwright J.D., 2007. Gene flow from transgenic maize to landraces in Mexico: An analysis. Agriculture Ecosystems and Environment 123, 109–115.

approach as a central principle in Mexican environmental policy making. The decision of the Mexican government on the *de facto moratorium* has been taken as an example of the implementation of the precautionary approach, however at the time other reasons contributed to the moratorium.

In 2001, a study[6] reported that maize landraces in Oaxaca, Mexico contained transgenes while sampling whole ears of *"criollo"* or native maize in southern Mexico. This research reported the presence of introgressed transgenic DNA constructs on native maize landraces grown in remote mountains of this area, part of the Mesoamerican centre of origin and diversification of this crop.[7] These findings have triggered the debate of gene flow from transgenic maize in Mexico while, on the other hand, authorities started monitoring activities and capacity building for government laboratory facilities.

The Mexican government lifted the moratorium for experimental field releases of GM maize in 2009. The specialized subcommittee in agriculture (SEA) was in charge to prepare recommendations based on risk assessment for GMOs.

The Law on Biosafety of Genetically Modified Organisms (LBOGM)[8] was published on March 18th, 2005. It has the purpose of regulating the activities of confined use, experimental release, release within a pilot program, commercial release, trading, importation and exportation of genetically modified organisms with the aim of preventing, avoiding or reducing the possible risks that these activities might cause to human health or to the environment and to biological diversity or animals, plants and aquatic organisms health.[9]

The Maize Special Protection Regime was included in the Regulations of the LBOGM which were published in March 19, 2008.[10] The Mexican Government developed a project financed by the Global Environmental Facility (GEF) from 2003 to 2005, which contributed to capacity building, among other issues, for detection, identification and quantification of GMOs. This initial effort leads to the creation of a laboratory on molecular genetics at the National Institute of Ecology in 2007 and the National Centre for Reference and Detection of Genetically Modified Organisms (CNRDOGM) in 2011.[11]

In Mexico the Inter- Secretarial Commission on Biosafety and Genetically Modified Organisms (CIBIOGEM) is an Inter- Ministerial Commission that has the aim of formulating and coordinating the policies of the Federal Public Administration

[6] Quist, D., Chapela I., 2001. Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico. Nature 414, 541–543.

[7] Ibid.

[8] Ley de Bioseguridad de los Organismos Genéticamente Modificados (LBOGM) published in D.O.F. March 18, 2005.

[9] Ibid., Article 1.

[10] Reglamento de la Ley de Bioseguridad de los Organismos Genéticamente Modificados (RLBOGM) published in D.O.F March 19, 2008 last amended and published in D.O.F on March 06, 2009.

[11] National Service of Agro Alimentary Health, Safety and Quality http://www.senasica.gob.mx/?id=2403 accessed 10 July 2013.

related to the biosafety of genetically modified organisms, it was created in 1999 by a Presidential Agreement.[12] Aside from the coordination of biosafety national policies, the CIBIOGEM also coordinates the implementation of regulated activities with GMOs such as: production, import, export, mobilization, transport, cultivation, consumption, and general use of GMOs and their products.[13]

Mexico acknowledges on its national regulatory framework, the society's right of access to information. On this issue, the LBOGM offers an adequate response through its articles 108 and 109, which also address Article 20 of the Cartagena Protocol.[14] In accordance to this legal mandate, Mexico has implemented the National Information System on Biosafety (NISB), which includes the National Register of GMOs. These are hosted within the web page of the CIBIOGEM and managed by its Executive Secretariat.[15] Additionally, the LBOGM establishes that after an application for a license to release GMOs to the environment is received, the application will be available to the public for consultation. Any person, including the governments of the federative entities where the respective release is supposed to take place, can express an opinion, supported technically and scientifically. These opinions will be taken into consideration by the corresponding Secretariats for the establishment of additional biosafety measures, in case that the license expedition for GMO release to the correspondent environment is issued, in the terms of the LBOGM.[16]

Food/Feed Security

The Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), is a Ministry from the Federal Executive Branch of the Government of Mexico, which has among its objectives supplying the domestic market with quality food, safe and accessible from its fields and seas. Moreover, the Secretariat created the Strategic Project for Food Security (SPFS) in connection with the Food and Agriculture Organization's (FAO) Special Program for Food Security.

The SPFS aims to improve food security and to contribute to sustainable poverty reduction in rural areas with high level of marginalization. The *Proyecto Estratégico*

[12] Acuerdo por el que se crea la Comisión Intersecretarial de Bioseguridad y Organismos Genéticamente Modificados con el objeto de coordinar las políticas de la Administración Pública Federal relativas a la bioseguridad y a la producción, importación, exportación, movilización, propagación, liberación, consumo y, en general, uso y aprovechamiento de organismos genéticamente modificados, sus productos y subproductos. Published in D.O.F. November 5, 1999.

[13] Inter-Ministerial Commission on Biosafety and Genetically Modified Organisms http://www.cibiogem.gob.mx/Paginas/default.aspx accessed 10 July 2013.

[14] Cartagena Protocol on Biosafety to the Convention on Biological Diversity 2226 U.N.T.S. 208; 39 ILM 1027 (2000); UN Doc. UNEP/CBD/ExCOP/1/3, at 42 (2000).

[15] Inter-Secretarial Commission on Biosafety and Genetically Modified Organisms http://www.cibiogem.gob.mx/eng/NISB/Paginas/default.aspx accessed 25 September 2013.

[16] LBOGM Article 33.

para la Seguridad Alimentaria (PESA)[17] in Mexico is promoted with technical support from the Food and Agriculture Organization of the United Nations.[18]

In Mexico transgenic crops like cotton and soy have been cultivated since 20 years ago. The objective of the Law on Biosafety of Genetically Modified Organisms and its Regulations[19] is to regulate the choice of agricultural production. In the case that this choice involves GMOs, environmental protection, human health, aquatic plant and animal health shall be guaranteed. The Inter-secretarial Commission on Biosafety of Genetically Modified Organisms in Mexico considers that transgenic crops represent one more option in agricultural production like the cases of the transgenic crops that are used in Mexico nowadays. In the case of transgenic cotton and soy cultivated in Mexico, preliminary data demonstrate a decrease on the use of pesticides and herbicides respectively.[20] The Mexican Government supports different types of agricultural production (conventional, organic, genetically modified etc.). However, any choice of agricultural production shall be adequate to the different conditions, soil production and productive vocation capacities.[21]

Legal Structure and Policy Concepts

In Mexico the Constitution guarantees the right to food which is defined in the Mexican Constitution as follows: "Every person has the right to nutritional, sufficient and quality nourishment. The State shall guarantee this".[22] In addition to the constitutional basis related to food security, the Constitution establishes the right to a healthy environment and addresses responsibility for damages and deterioration of the environment.[23] The LBOGM establishes that the State has the obligation of guaranteeing the right of every person to live in an adequate environment for his nourishment, health, development and wellness.[24]

With the aim of protecting the environment and biological diversity, the Mexican State must adopt the precautionary approach in agreement with its capacities and

[17] Strategic Project for Food Security, see http://www.pesamexico.org/

[18] Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food http://www.sagarpa.gob.mx/desarrolloRural/AsistenciaCapacitacion/Paginas/pesa.aspx accessed 14 June 2013.

[19] Law on Biosafety of Genetically Modified Organisms 18 March 2005 http://www.diputados.gob.mx/LeyesBiblio/ref/lbogm.htm and REGULATIONS to the Genetically Modified Organisms Biosafety Law 6 March 2009 http://www.diputados.gob.mx/LeyesBiblio/regla.htm

[20] See Traxler G., Godoy-Avila S. Transgenic Cotton in Mexico, AgBioForum, 7(1&2): 57–62, 2004.

[21] Intersecretarial Commission on Biosafety of Genetically Modified Organisms http://www.cibiogem.gob.mx/Paginas/FAQs.aspx accessed 14 June 2013.

[22] Constitución Política de los Estados Unidos Mexicanos Article 4 (III). Published in D.O.F. February 5, 1917 last amended and published in D.O.F. October 8, 2013.

[23] Constitution of Mexican United States Article 4 (IV).

[24] LBOGM Article 9 (II).

taking into consideration the compromises established in international conventions and agreements in which the United Mexican States is a participant. In cases of severe or irreversible damage, the lack of absolute scientific certainty must not be the reason for deferring the adoption of effective measures to prevent the degradation of the environment and biological diversity. Such measures shall be adopted in conformity with the previsions and administrative procedures established in the LBOGM.[25] Furthermore, in the application of this law, is established in its Article 9 that the Mexican State acts in a cautious and prudent manner and based on scientific and technical foundations to prevent, reduce and avoid the possible risks that the activities with GMOs may originate to human health or to the environment and biological diversity.[26]

Outline of the Relevant Laws and Regulations

National Regulatory Laws and Complementary Legal Instruments

- Political Constitution of the Mexican United States.[27]
- Law on Biosafety of Genetically Modified Organisms.[28]
- Regulations to the Genetically Modified Organisms Biosafety Law.[29]
- Agreement to determine Maize Centres of Origin and Maize Centres of Genetic Diversity.[30]
- Agreement to determine information related to activities of contained use of GMOs.[31]
- CIBIOGEM's Internal Regulations.[32]
- CIBIOGEM's Operational Regulations.[33]

[25] Ibid Article 9 (IV).

[26] Ibid Article 9 (XV).

[27] Constitución Política de los Estados Unidos Mexicanos published in D.O.F February 5, 1917. Last amended and published in D.O.F. October 8, 2013.

[28] Ley de Bioseguridad de Organismos Genéticamente Modificados published in D.O.F. March 18, 2005.

[29] Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados published in D.O.F March 19, 2008. Last amended and published in D.O.F March 6, 2009.

[30] Acuerdo por el que se determinan los Centros de Origen y Centros de Diversidad Genética del Maíz published in D.O.F. November 2, 2012.

[31] Acuerdo por el que se determina la información y documentación que debe de presentarse en el caso de realizar actividades de utilización confinada y se da a conocer el formato único de avisos de utilización confinada de organismos genéticamente modificados published in D.O.F. April 15, 2011.

[32] Reglamento de la Comisión Intersecretarial de los Organismos Genéticamente Modificados published in D.O.F. November 28, 2006.

[33] Acuerdo por el que se expiden las Reglas de Operación de la Comisión Intersecretarial de los Organismos Genéticamente Modificados published in D.O.F. December 5, 2007.

- Official Mexican Standard NOM-164-SEMARNAT/SAGARPA-2013, That establishes the characteristics and content of the results report of the environmental releases of genetically modified organisms in relation to their likely risks to the environment and biological diversity and additionally to animal, aquatic and plant health.[34]
- Operational Rules of the "Fund to Support and Develop Scientific and Technological Research in Biosafety and Biotechnology" (*FONDO CIBIOGEM*).[35]
- Regulations of the Mexican Network for Monitoring of Genetically Modified Organisms.[36]
- Law on Science and Technology.[37]
- CONACYT's (National Council on Science and Technology) Organic Statute.[38]
- Federal Animal Health Law.[39]
- Federal Plant Health Law.[40]
- Law of Organic Products.[41]
- Regulations to the Law of Organic Products.[42]
- Federal Law on the Production Certification and Trade of Seeds.[43]
- Law of Sustainable Rural Development.[44]

[34] NORMA Oficial Mexicana NOM-164-SEMARNAT/SAGARPA-2013, Que establece las características y contenido del reporte de resultados de la o las liberaciones realizadas de organismos genéticamente modificados, en relación con los posibles riesgos para el medio ambiente y la diversidad biológica y, adicionalmente, a la sanidad animal, vegetal y acuícola. http://www.conacyt.gob.mx/cibiogem/images/cibiogem/normatividad/vigente/2014_01_03_MAT_semarnat.pdf

[35] Reglas de Operación del Fideicomiso denominado "Fondo para el fomento y apoyo a la investigación científica y tecnológica en Bioseguridad y Biotecnología" FONDO CIBIOGEM aproved and issued in February 12, 2009 by agreement No.AS-XXVII-07/09.

[36] Reglas de operación y funcionamiento de la Red Mexicana de Monitoreo de los Organismos Genéticamente Modificados issued June 23, 2009 http://www.cibiogem.gob.mx/Norm_leyes/Documents/REGLAS_OPERACION_REDMONITOREO.pdf acceded 28 November 2013.

[37] Ley de Ciencia y Tecnología published in D.O.F. June 5, 2002. Last amended and published in D.O.F. January 28, 2011.

[38] Estatuto Orgánico del Consejo Nacional de Ciencia y Tecnología published in D.O.F. June 10, 2010.

[39] Ley Federal de Sanidad Animal published in D.O.F. July 25, 2007. Last amended and published in D.O.F. June 7, 2012.

[40] Ley Federal de Sanidad Vegetal published in D.O.F. January 5, 1994. Last amended and published in D.O.F. November 16, 2011.

[41] Ley de Productos Orgánicos published in D.O.F. February 7, 2006.

[42] Reglamento de la Ley de Productos Orgánicos published in D.O.F. April 1, 2010. Errata D.O.F. April 8, 2010.

[43] Ley Federal de Producción Certificación y Comercio de Semillas published in D.O.F. June 15, 2007.

[44] Ley de Desarrollo Rural Sustentable published in D.O.F. December 7, 2001. Last amended and published in D.O.F. January 12, 2012.

- Agreement to create the Scientific Technical Committee of The Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food, on Genetically Modified Organisms.[45]
- Notice of Annulment of the Official Mexican Standard NOM-056-FITO-1995.[46]
- Agreement to delegate specific powers and functions between directorates of the Secretariat of Agriculture.[47]
- Model Guidelines to apply for a permit for Experimental Release of Genetically Modified Maize.[48]
- Guidelines to fill in an application for permit for experimental release to the environment of Genetically Modified Organisms.[49]
- General Law of Ecological Equilibrium and Environmental Protection.[50]
- Regulations to the General Law of Ecological Equilibrium and Environmental Protection regarding environmental impact assessments.[51]
- General Law on Sustainable Forest Development.[52]
- General Health Law.[53]
- Regulations for Sanitary Control of Products and Services.[54]

[45] Acuerdo por el que se crea el Comité Técnico Científico de la Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación en materia de organismos genéticamente modificados published in D.O.F. June 22, 2009.

[46] Aviso de cancelación de la Norma Oficial Mexicana NOM-56-FITO-1995, Por la que se establecen los requisitos fitosanitarios para la movilización nacional, importación y establecimiento de pruebas de campo de organismos manipulados mediante la aplicación de ingeniería genética, publicada el 11 de Julio de 1996 published in D.O.F June 22, 2009.

[47] Acuerdo por el que se delegan en el titular del Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria y en sus directores generales de Salud Animal, salud Vegetal e Inocuidad Alimentaria, Acuícola y Pesquera, las facultades y funciones que se indican, published in D.O.F. June 22, 2009.

[48] Guía Modelo para la Solicitud de Permiso de Liberación Experimental de Maíz Genéticamente Modificado, published June 9, 2012 and Guía Modelo para la Solicitud de Permiso de Liberación al Ambiente de Maíz Genéticamente Modificado en Programa Piloto published May 14, 2013 http://www.cibiogem.gob.mx/Norm_leyes/Paginas/default.aspx acceded 29 November 2013.

[49] Guías para la Integración de Solicitudes de Permiso de liberación al Ambiente de Organismos Genéticamente Modificados published in May 9, 2013 http://www.cibiogem.gob.mx/Norm_leyes/Paginas/default.aspx acceded 29 November 2013.

[50] Ley General de Equilibrio Ecológico y Protección al Ambiente published in D.O.F. January 28, 1988. Last amended and published in D.O.F. November 5, 2013.

[51] Reglamento de la Ley General de Equilibrio Ecológico y la Protección al Medio Ambiente en Materia de Evaluación de Impacto Ambiental published in D.O.F. April 26, 2012. Errata published in D.O.F. April 27, 2012.

[52] Ley General de Desarrollo Forestal Sustentable published in D.O.F. February 25, 2003.Last amended and published June 7, 2013.

[53] Ley General de Salud published in D.O.F. February 7, 1984 last amended and published in D.O.F. April 24, 2013.

[54] Reglamento de Control Sanitario de Productos y Servicios published in D.O.F. August 9, 1999.

- Regulation on Health Inputs.[55]
- Regulations to the General Health Law on Publicity.[56]
- Regulations to the General Health Law on Health Research.[57]
- Federal Penal Code.[58]
- Federal Law on Environmental Liability.[59]

International Law

- The Convention on Biological Diversity, adopted on 29 January 2000, entered into force on 29 December 1993.[60]
- Cartagena Protocol on Biosafety to the Convention on Biological Diversity adopted on 29 January 2000, entered into force on 11 September 2003.[61]
- Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress, adopted 16 October 2010.[62]

Approval Systems

Requirements Contained Use of GMO's

Conditions of Use

Confined use includes those activities in which the genetic material of an organism is modified or, once done, this modified living organism is cultivated, stored, used, processed, transported, traded, destroyed or eliminated as long as in the undertaking of these activities physical barriers are employed, or a combination of these and chemical or biological barriers, with the aim of limiting in an effective manner its

[55] Reglamento de Insumos para la Salud published in D.O.F. January 2, 2008. Last amended and published in D.O.F. October 9, 2012. Last amended and published in D.O.F. October 19, 2011.

[56] Reglamento de la Ley General de Salud en materia de Publicidad published in D.O.F. May 4, 2000. Last amended and published in D.O.F. January 19, 2012.

[57] Reglamento de la Ley General de Salud en materia de investigación para la Salud http://www.cibiogem.gob.mx/Norm_leyes/Documents/normatividad-SSA/071006RLSMIS.pdf acceded November 24, 2013.

[58] Código Penal Federal published in D.O.F. August 14, 1931. Las amended and published in D.O.F. October 30, 2012.

[59] Ley Federal de Responsabilidad Ambiental published in D.O.F. July 7, 2013.

[60] Mexico signed the Convention on Biological Diversity in June 13, 1992 ratifying in March 11, 1993. http://www.cbd.int/convention/parties/list/ acceded 27 September 2013.

[61] Mexico signed the Cartagena Protocol in May 24, 2000 ratifying in August 27, 2002. http://bch.cbd.int/about/countryprofile.shtml?country=mx acceded 27 September 2013.

[62] Mexico signed the Nagoya-Kuala Lumpur Supplementary Protocol in March 12, 2012 ratifying in September 26, 2012. http://bch.cbd.int/protocol/parties/#tab=1 acceded 27 September 2013.

contact with the population and the environment.[63] The confined utilisation of GMOs may have the following purposes: teaching, scientific and technological research, industrial use and trading.[64]

Notification Requirements

The following activities require a notification:

I. GMOs handled, originated and produced for teaching purposes or for scientific and technological research;
II. The integration of the internal biosafety commissions, including the name of the person or persons responsible of such commissions;
III. The first time a laboratory or facility is used for teaching or for scientific and technological research in which GMOs are handled, originated or produced;
IV. The production of GMOs for industrial processes, and
V. The first time specific facilities are used for the GMO production referred.[65]

The LBOGM establishes a notification requirement for the importation of GMOs to be used in a confined facility for industrial or commercial purposes, in the following cases:

I. GMOS not requiring a permit, given that they will be exclusively used in a confined manner, and therefore, are not imported to be released to the environment, and
II. GMOs not requiring sanitary authorisation given that they will not be for human use or consumption of for public health aims.[66]

Authorisation Requirements

The confined utilisation of GMOs and the importation of such organisms for this activity can be carried out when the internal commission of biosafety or the importer presents the respective notification to the relevant Secretary. Once the notification is presented, the relevant Secretary may determine, in a specific case, and based upon scientific and technical evidence that: the activity must be suspended, the adoption and implementation of additional biosafety measures for that case, or the prohibition of the confined utilisation of a determined genetically modified organism or its importation for this activity.[67]

[63] LBOGM Article 3 (XXXIV).
[64] Ibid Article 73.
[65] Ibid Article 79.
[66] LBOGM Article 80.
[67] Ibid Articles 83–84.

Requirements for Releases of GMOs into the Environment

Requirements for Research and Development Purposes

Conditions of Use

Mexico implements a step by step approach for release in to the environment of GMO's based on three stages: (i) experimental release (ii) release in a pilot program and (iii) commercial release. This is a procedure for approval of permits for the release of GMO's in to the environment. However, this approach refers from small scale release to different scales of field testing and pre-commercial release. The permit for the commercial release to the environment of a determined GMO entails the authorisation for its commercialization and trading of such organism and the products containing it, in the terms of the LBOGM.[68]

Experimental Release (Field Trial) The introduction, intentional and permitted, into the environment of a genetically modified organism or a combination of them, in which containment measures have been adopted, such as physical barriers, or a combination of these with chemical or biological barriers, should limit their contact with the population and the environment. This introduction is exclusively for experimental purposes, in the terms and conditions within the respective permit.[69]

Release Within a Pilot Program (Pre-commercial Stage) The introduction, intentional and permitted, into the environment of genetically modified organisms or a combination of them, with or without containment measures, such as physical barriers or a combination of these with chemical and biological barriers, should limit their contact with the population and the environment. This introduction is previous to the commercial release of such organism or group of organisms, within the authorised areas and in the terms and conditions contained in the respective permit.[70]

Commercial Release The introduction, intentional and permitted into the environment of a genetically modified organism or a combination of them, without the adoption of containment measures such as physical barriers, or a combination of these with biological or chemical barriers, should limit their contact with the population and the environment. This introduction has commercial, production, bioremediation, and industrial purposes, or others different from experimental release and release within a pilot program, in the terms and conditions issued in the respective permit.[71]

[68] Ibid Article 59.

[69] Ibid Articles 3 (XVII).

[70] Ibid Articles 3 (XVIII).

[71] LBOGM Article 3 (XVI).

Notification and Authorisation Requirements

Experimental Release (Field Trial) Permit applications for the experimental release of GMOs to the environment, including their importation for this activity, must be accompanied by the following information:

I. Characterization of the GMO, in which it must be considered what is established in the official Mexican norms derived from the LBOGM for each case;
II. Identification of the zone where GMOs are to be experimentally released, including the specifications about the total area in which the release will take place,
III. A study of the possible risks that the release of GMOs could have on the environment and on the biological diversity. Furthermore, in those cases in which SAGARPA has competence, the study must include possible risks that the liberation of such organisms could cause to the health of animals, plants or aquatic organisms;
IV. The measures and procedures for monitoring the activity and biosafety that will be carried out when the activity takes place and those after the release;
V. In its case, the preceding GMO release information from other countries;
VI. In its case, the considerations, concerning the risks of available alternative technologies to treat the problem for which the genetically modified organism to be released was built, will be presented, and
VII. The information determined, for each case, by the Mexican Official Norms derived from the LBOGM.[72] Additionally to the requirements of the LBOGM, the application for a permit for experimental release of a GMO shall include the information required for this purpose in the Regulations to the LBOGM, particularly the ones in Article 16.[73]

In order to obtain a permit for experimental release to the environment, it is a requirement to have the GMO authorisation issued by the Secretariat of Health in accordance with the LBOGM, when such organism is destined for public health purposes or for bioremediation, or if it is a GM maize. The interested person may start the procedures to obtain such license from the competent Secretariat, but the permit will not be issued until the authorisation from the Secretariat of Health is granted.[74]

In addition to what is previously established, the persons interested in the importation of GMOs for their experimental release into the environment, must enclose with their application the information and documentation granting that the GMO is permitted under the legislation of the country of origin, at least for its release in an

[72] Ibid Art. 42.

[73] RLBOGM Art. 16 (I a-t).

[74] Ibid.

experimental stage, enclosing for such effects the authorisation or official documentation that supports this situation.[75]

Pilot Program (Pre-commercial Stage) The application of a permit to carry out the release of a GMO to the environment within a pilot program, including its importation for this activity, must be accompanied by the following information:

I. The permit for the experimental release of a determined GMO;
II. Reference and considerations on the report of the results of the experimental release or releases in relation to the possible risks to the environment and biological diversity, and additionally, to animal, plant and aquatic organisms health in the cases in which SAGARPA is the competent institution in accordance with the LBOGM;
III. Information relative to the following:
    (A) The total amount of GMO to be released;
    (B) Handling conditions given to the GMO, and
    (C) Identification of the zones where the GMO is to be released, including a specification of the area or total areas where the release will take place.
IV. Monitoring and biosafety measures to be undertaken during and posterior to the release of such activity, and
V. The information that for each case is determined by the Mexican Official Norms derived from the LBOGM.[76] The former with the aim that the corresponding Secretariats have the information available to perform the analysis and assessment of the possible risks to the environment and biological diversity or to the health of animals, plants and aquatic organisms according to the terms of the LBOGM.

Furthermore, in order to obtain the permit for the release to the environment within a pilot program, it will be a requirement that the applicant has the authorisation of the Secretariat of Health for the specific GMO in accordance with the LBOGM when such organism is meant to be for human use or consumption. The interested person could start the administrative procedures to obtain such license in the competent Secretariat, but this will not be granted until the person gives proof of the authorisation from the Secretariat of Health in the respective file. Additionally to the requirements of the LBOGM the application for a permit for a pilot program, of a GMO will include the information required for this purpose in the Regulations to the LBOGM.[77]

[75] Law on Biosafety of Genetically Modified Organisms Article 43.

[76] Ibid Art.50.

[77] RLBOGM Art.17.

Commercial Release The authorisation application to undertake the commercial release of GMOs to the environment, including its importation for this activity, must be accompanied by the following information:

I. The permits for the releases, experimental and within a pilot program, of the determined GMO;
II. The reference and considerations on the reports with the results of the experimental release and release in a pilot program that had been carried out, in the terms of the licenses referred in the former fraction;
III. Specific instructions and recommendations for the storage, transport, and in its case, handling;
IV. In its case, the conditions for its release and trading;
V. In its case, the presentation of the considerations on the risks of the available alternative technologies to contend with a problem for which the GMO to be released was designed;
VI. In its case, the information the applicant has available on data or results related to the trading of the determined GMO in other countries, and
VII. The additional information determined by the Mexican Official Norms derived from the LBOGM. The former with the aim that the corresponding Secretaries have the information available to perform the analysis and assessment of the possible risks to the environment and biological diversity or to the health of animals, plants and aquatic organisms.[78]

The interested persons in the importation of GMOs for commercial release, besides what is established in the previous article, must enclose the information and documentation proving that the GMO is authorised for its trading in accordance with the legislation of the country of origin, and for this matter must include the authorisation or official documentation supporting this situation.[79]

Place in to the Market

Trading or Commercialization The introduction into the market of genetically modified organisms to be distributed and consumed as products or merchandises, without having the intention of releasing them into the environment, independent of its lucrative character and of the legal title under which it is made.[80]

[78] LBOGM Article 55.

[79] Ibid Article 56.

[80] See supra the authorisation to place in to the market is granted with the authorisation for the commercial release of GMOs.

Requirements for Applying GMOs in Food or Feed

Conditions of Use

GMO's destined for the processing of foods for human consumption are subject to authorisation. For the effects of the LBOGM, GMOs will also be considered for human use or consumption when though they are for animal utilisation may be directly used for human consumption.[81]

Authorisation

The application for a GMO authorisation must be accompanied by the following requirements:

I. The study of the possible risks that the use or consumption by humans of the determined GMO might have on human health, including scientific and technical information related to its innocuousness, and
II. Other requirements determined in the Mexican official norms derived from the LBOGM.

The guidelines, criteria, characteristics and requirements of the studies on the possible risks that GMOs might have on human health will be determined by the Secretariat of Health in the Mexican official norms issued in accordance with the LBOGM.[82]

In the case of applications of GMO authorisations to allow its importation for the purposes of GMO's destined for the processing of foods for human consumption, the interested person must enclose the information and documentation demonstrating that the GMO is authorised in conformity with the legislation of the country of origin. If this is not the case, the interested person will have to declare the inexistence of such situation and present elements to the Secretariat of Health may use as foundations to resolve the authorisation application.[83]

Once the Secretariat of Health receives an authorisation application, and provided that it complies with all the information and requirements established in the LBOGM, it will remit it to the Registry to be inscribed and published.[84] The Secretariat of Health will issue its resolution once it has analysed the information and documentation provided by the interested person.[85]

[81] Law on Biosafety of Genetically Modified Organisms Article 91.

[82] Law on Biosafety of Genetically Modified Organisms Article 92.

[83] Ibid Article 93.

[84] Ibid Article 94.

[85] Ibid Article 95.

Threshold Values

Mexico's Biosafety Law and the Implementation Rules do not specify a threshold limit for Genetically Modified seeds. In Mexico the Official Mexican Standards (NOMs) are binding technical regulations. These NOMs regulate products, processes or services, when these may pose a risk to persons, animals, plants or the environment. SAGARPA published on May 30, 2014 the Official Mexican Standard NOM-001-SAG/FITO-2013[86]; the objective of this NOM is to establish the criteria, procedures and specifications, for the development of guidelines for varietal description, and regulations for determining the quality of planting seeds according to international standards. Moreover, the Federal Plant Variety Law and the Federal Law of Production Certification and Seed Trade both establish that a Mexican Official Standard should be the regulatory instrument that should establish the criteria, procedures and specifications for the development of guidelines for varietal description, and regulations for determining the quality of planting seeds.

Restrictions on GMO Environmental Release

The Law on Biosafety of Genetically Modified Organisms in its fourth title specifies the restricted zones.[87] Furthermore, the Regulations to the Genetically Modified Organisms Biosafety Law and the Agreement to determine Maize Centres of Origin and Maize Centres of Genetic Diversity, will also apply together with the agreements on the designation of a protected area and precautionary measures established by the Secretariat of Environment and National Resources (SEMARNAT) and SAGARPA.

(a) Centre of Origin and Genetic Diversity

In Mexico the restricted areas for the environmental release of GMOs are (i) centres of origin or genetic diversity (ii) natural protected areas (iii) GMO free zones.

The release of GMOs is permitted[88] in restricted areas when the GMOs intended to be released are distinct from native animal and plant species provided that these releases do not cause any negative effects on human health or biological diversity.

How to determine a centre of origin and genetic diversity will be agreed jointly between SAGARPA and SEMARNAT based on the information in their data or in their database including the National Statistics and Geography

[86] Norma Oficial Mexicana NOM-001-SAG/FITO-2013, Por la que se establecen los criterios, procedimientos y especificaciones para la elaboración de guías para la descripción varietal y reglas para determinar la calidad de las semillas para siembra. Published in D.O.F. May 30, 2014.

[87] Law on Biosafety of Genetically Modified Organisms Title IV Articles 86–90.

[88] LBOGM Art.88.

Institute, National Institute of Forestry and Agriculture Research, the National Institute for Ecology and Climate Change, the National Commission for the Use and Knowledge of Biodiversity and the National Forestry Commission and international treaties and agreements related.[89] In centres of origin and genetic diversity of animal and plant species, releases of GMOs will be permitted only when these GMOs are different from the native species, and provided that this release will not affect human health or biological diversity.

(b) Natural Protected Areas

In natural protected areas activities with GMOs will only be permitted for bioremediation purposes in the cases that plagues or polluters could put at danger the existence of animal, aquatic or plant species and these GMOs where specifically created to avoid or combat that situation. However, activities with GMOs are banned in core areas of the Natural Protected Areas.

(c) GMO-free zones

GMO-Free zones may be established for the protection of organic agricultural products and others of interest to the soliciting community, in agreement with the following general guidelines:

I. The GMO-free zones will be established when GMOs of the same species to the ones resulting from production of organic agricultural products coincide, and when it is scientifically and technically demonstrated that their coexistence is not viable or that they would not comply with the normative requirements for their certification.
II. Such zones will be determined by SAGARPA by means of agreements to be published in the Federal Official Journal, with a previous dictate from CIBIOGEM, and the opinion of the National Commission for the Understanding and Utilisation of Biodiversity, taking into consideration what is established in the Mexican Official Standards relative to organic agricultural production.

Implementation and Enforcement

Infractions to the precepts of the Law on Biosafety of Genetically Modified Organisms,[90] its rules and regulations and to the Mexican Official Standards derived from it will be sanctioned administratively by the competent Secretaries with one or more of the following sanctions:

- Administrative fines.
- Temporal or definitive closure, partial or total, of the facilities where infractions were committed whenever: (A) The infractions cause possible risks or adverse effects to human health, or to biological diversity, or to the health of animals,

[89] Ibid Art. 86.

[90] LBOGM Article 120.

plants or aquatic organisms; (B) The infringer did not comply with the terms or conditions established by the competent Secretaries, nor with the security measures or those of urgent application ordered by the Secretaries, or (C) The non-compliance of one or more of the security or of urgent application measures, implemented by the competent Secretaries, is reiterative.
- The confiscation of the instruments, exemplars, obtained organisms or products directly related to the committed infractions;
- The suspension or revocation of the corresponding permits and authorisations. Administrative arrest up to 36 h.
- Prohibition of the experimental release, release within a pilot program or the commercialization of GMOs and products containing them.

Labelling Regime

Labelling

Genetically Modified Organisms or products containing genetically modified organisms, authorised by the Secretariat of Health given their innocuousness in the terms of the LBOGM and to be used directly for human consumption, must guarantee the explicit reference of "genetically modified organisms" and indicate in the label information regarding their food composition or their nutritious properties. This applies when these characteristics are significantly different from the respective conventional products; compliance is required with the additional general labelling requirements in accordance to the Mexican Official Standards issued by the Secretariat of Health in agreement with what is established in the General Health Law and its regulatory provisions, with the participation of the Secretary of Economy.[91]

Legislation Addressing Labelling Fraud

The evaluation with conformity of such Mexican Official Standards must be carried out by the Secretary of Health, Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food and the Secretary of Economy in the field of their respective competences, and the accredited and approved persons in agreement with what is established in the Federal Law on Metrology and Normalization depending of the NOM applying to the case.[92]

[91] LBOGM Article 101.

[92] Ibid Article 101 para. 4.

Liability

Genetic Technology

Federal Law on Environmental Liability (LEL)

The Federal Law on Environmental Liability (LEL) entered into force in July 2013.[93] At the same time, the LEL amended some procedural provisions in few federal laws. The most significant amendments were made to the General Law for Ecological Equilibrium and Environmental Protection, specifically, new procedural rules on compensation and restoration to allocate environmental liability according to the LEL.[94] The LEL aims to provide a legal framework to address environmental damage, recognizing the difference between economic damage (traditional damage) and pure ecological damage.[95]

Scope of the regime.–

The LEL regulates liability arising from environmental damage, restoration and compensation when it proceeds according to the judicial procedures provided in the Federal Constitution.[96]

Standards of liability.–

The LEL imposes strict and fault based liability for those who cause damage to the environment. Fault based liability will be triggered in case of breach of statutory duty.[97] A person that causes environmental damage when the latter is caused by any of the activities listed in Article 12[98] will be held strictly liable for environmental damage.

Definition of Environmental damage.–

Environmental damage is defined as: "The measurable adverse loss, deterioration, detriment, affectation, or modification of the chemical, physical or biological conditions of habitats, ecosystems, natural elements and resources, as well as of the interaction relationships and the environmental services provided by the same."[99]

Law on Biosafety of Genetically Modified Organisms

As established *supra*, the entry into force of the LEL amended some provisions of the most important environmental regulations. However, the Law on Biosafety of Genetically Modified Organisms remained without any changes. The LBOGM

[93] Federal Law on Environmental Liability DOF 7-06-2013.

[94] General Law for Ecological Equilibrium and Environmental Protection Art. 168–169,176.

[95] Federal Law on Environmental Liability Art.1 para.3.

[96] Federal Law on Environmental Liability Article 1 para.1.

[97] Ibid Article 11.

[98] Ibid Article 12.

[99] Id.

addresses civil liability for damage against persons, and goods for GMO-related activities as follows: "Any person, having plain knowledge that he/she is dealing with GMOs, causes damage to third persons in his/her assets or health, by the misuse or mishandling of such organisms will be held responsible and obliged to compensation in the terms of the federal civil legislation.[100]

In addition, the LBOGM deals with environmental damage under the same article providing that the same obligation will assume the person that causes damage to the environment or biological diversity, by the misuse or mishandling of GMOs. Moreover, the provisions laid down in Article 203 of the General Law for the Ecological Equilibrium and the Protection of the Environment, will apply. These provisions establish the obligation to compensate in conformity with the applicable civil legislation.[101]

Finally, administrative sanctions will be implemented without detriment, in its case, of the punishments corresponding to acts or omissions constitutive of infractions to this Law, when theses constitute of punishment in accordance with the applicable provision in the Federal Penal Code.[102]

Product Liability

The health control of derived products and confined productive processes in which GMOs intervene, for human or animal usage and consumption, are subject to the provisions in the General Health Law and its rules and regulations applicable to all products and processes.[103] Moreover, the General Health Law establishes that the Secretary of Health might be notified in all the cases of use of GMOs and their products for human consumption. Furthermore, all the specifications, characteristics and labelling of these products will be established in the relevant Official Mexican Standards.[104]

Summary

Under Mexico's Biosafety Law and its Implementation Rules a methodological approach *Step by step* is established in which all GMOs to be commercially released must be previously submitted to satisfactory tests concerning risks studies, assessment of risks and reports of the results applicable to the undertaking of activities of

[100] LBOGM Article 121 para. 1.

[101] Id.

[102] LBOGM Article 121 para. 7.

[103] Law on Biosafety of Genetically Modified Organisms Article 6 (IV).

[104] General Health Law Article 282 bis (1–2).

experimental release and release within a pilot program of the determined organisms, in the terms of the LBOGM.[105]

The evaluation of genetically modified organisms supported with scientific and technical evidence is done individually *case by case.*

On April 9, 2010, the Mexican Government published a notice in the Federal Official Journal announcing the application of the 2010 National Normalization Program.[106] This annual program seeks to reduce the number of NOMs and other regulations in an effort to promote more streamlined national regulations. Considering the importance of maize in Mexico as a centre of origin and the lack of an official threshold for GMOs in Mexico, standardization of threshold for agricultural products should be included in the National Normalization Program. Scientific authorities should reach consensus of the most convenient threshold for agricultural products in Mexico instead of case by case approach without any uniform standard, specifically for GMOs.

The recent entry in to force of the Law of Environmental Liability represents a big step for Mexico to have access to a suitable regime to address environmental damages. The concept of environmental damage, related to possible damages caused by GMO's, has to be accurate to the context of possible damage in specific cases and further study of the applicable standard of liability shall be done.

The Mexican Biosafety legal framework is changing and adapting to develop and apply biotech products for the resolution of national problems and protection and sustainable use of species that have their centre of origin and genetic diversity in Mexico.

How to take advantages of every production system, including traditional, organic, and improved varieties including conventional and biotech will be critical to assure self-sufficiency in key crops like maize.

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Part IV
National Reports – Asia

Chapter 12
Genetic Technology and Food Safety in Taiwan: Country Report: Taiwan

Anton Ming-Zhi Gao and Katherine Yuhh-Chihh Juang

During the course of the past year, numerous food scandals have served to raise the awareness of the potential dangers of GM food in Taiwan. The purpose of this article is to review the existing legal regime applicable to not only GM Food, but also the GM research in Taiwan, and to provide updated info on the latest development of GM food legal regime. It remains to be seen if the amended laws will be implemented effectively. It also remains to be observed whether anti-GM sentiment and legal developments will negatively impact Taiwan's domestic GM industries.

General Information

The Use of GMO in Food Production

The Use of GMO in Taiwan's Food Industry

In Taiwan, there are three main categories of GMO food products: GMO plants, GMO animals, and GMO aquaculture crops and livestock. Taiwan imports 2.5 million tonnes of soybeans and 4.8 million tonnes of corn each year. An estimated 93 %

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and 40 % of these imports are GMO, respectively.[1] Taiwan has its own domestic GMO research industry; the crops being developed include papaya, bananas, watermelon, sweet melon, bitter gourd, tomatoes, broccoli, fur soybeans, rice, potatoes, chrysanthemum, *Oncidium* (a genus of orchids), and calla lily. GMO livestock such as cows, pigs, milk-producing sheep, and aquaculture crops and livestock including loach, catfish, abalone, shrimp, and fluorescent fish are also being studied.[2]

In spite of the existence of an established GMO-research industry, only soy & corn have been approved as food by the Taiwan Food and Drug Administration.[3] As such, the other GMO crops and livestock remain at the pre-market stage of research and development.

Public Attitudes Towards GMO

As in many other countries, GMO is a controversial topic in Taiwan. Numerous studies on public perceptions in regards to different aspects of research and development (R&D) and food deployment for GMO products have been conducted by the government through the Ministry of Health and Welfare (MOHW; which, prior to the government reform of 23 July 2013, was known as the Department of Health (DOH)), the leading national science academy (Academia Sinica), and other independent researchers.

In 2000, the MOHW launched a pioneering study that studied public perceptions of GMO food and its safety.[4] The results showed 68.1 % of respondents had heard of GMO. However, more than half did not have an understanding of the advantages or disadvantages of GMO food. Even so, 61.6 % of respondents expressed concern about the safety of GMO food. Some 66.9 % of those surveyed were worried about the potentially negative effects on human health that could result from the consumption of pest-resistant GMO crops. Among those surveyed, female respondents between the ages of 30 and 39 expressed the highest level of concern for food safety issues.

In 2005, a study conducted by Academia Sinica focused on public acceptance of various GMO products.[5] The study found that the GMO products that attracted higher levels of acceptance were ornamental flowers (86.2 %), ornamental animals (52.9 %), edible plants (52.9 %), and edible animals (22.2 %). Yet, when respondents

[1] http://www.taifer.com.tw/search/051001/48.html

[2] http://www.pabp.gov.tw/AreaBus/libA/aa503.asp

[3] The approved GMO corn and soy in Taiwan, see: https://consumer.fda.gov.tw/Food/GmoInfo.aspx?nodeID=167

[4] The Department of Health (衛生署) (2000), 'The Study on Public Perception on Biotechnology and GMO Food' (民眾對生物科技及基因改造食品的認知及態度), available at: http://food.doh.gov.tw/gmo/gallup.htm

[5] Academia Sinica (2005), The Opinion Poll on Biotechnology in Agricultural Sector and the Establishment of Database (農業生物科技意向調查與資料庫建置之規劃), Taipei: FU-Tsu-Tang Publisher (台北:傅祖壇).

were asked about unacceptable GMO products, the survey outcome ranked edible animals (70.5 %) first, followed by edible plants (41 %), ornamental animals (39 %), and ornamental flowers (9 %). The results demonstrated that a relatively high level of concern for the safety of eating GMO products exists. In 2007, there was a further study carried out on consumption sentiments relating to GMO products. Telephone-based interviews revealed that almost 90 % of interviewers would be not willing to risk their health for cheaper GMO food.[6] The study also found that among the respondents who believed in the ecological or health benefits endorsed by scientists, as much as 80 % would nevertheless prefer not to buy GMO food.

Another study addressed the issue of GMO research and development.[7] The results showed that 78 % of those surveyed supported the view that humans should not change the 'rules of nature'. Even though 83 % of the respondents believed that technology could improve human life, 45 % still believed that the preservation of the natural environment was more important than technological development.

Overall, the research suggests that there is widespread concern about GMO R&D and GMO food. The research also suggests that there are divergent views on GMO food and products. In response, the Taiwan government has adopted a specific strategy for GMO products and research in Taiwan.

The Position of the Taiwan Government on GMO Food Production

The Taiwan government recognises the potential risks of GMO foods or products. For example, the government recognises the possibility of allergic reactions from GMO food in persons sensitive to allergens. The government also recognises the legitimacy of biodiversity concerns regarding the possibility of GMO fish threatening other aquaculture livestock. In general, the Taiwan government has adopted a moderate approach in adopting a regulatory framework for GMO R&D, food, and production.[8] Arguably, appropriate incentives and regulations have both been provided, rather than merely restrictive or punitive provisions.

The first key part of this framework was the establishment of a cross-ministerial working group. The Executive Yuan (i.e., the highest executive body in Taiwan) worked with a number of government authorities (such as the Ministry of Science and Technology (MOST; which was known as the National Science Council (NSC) prior to the 2013 government reform), the MOHW, and the Agricultural Council (AC)) to establish a cross-ministerial working group responsible for developing a GMO-products regulatory regime.

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[6] Academia Sinica (2007)。(的認知及態度), available at: http://food.doh.gov.tw/gmo/gallup.htm
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[7] Academia Sinica (2003)。The Opinion Poll on Biotechnology in Agricultural Sector and the Establishment of Database (農業生物科技意向調查與資料庫建置之規劃), Taipei: FU-Tsu-Tang Publisher (台北:傅祖壇).

[8] http://www.pabp.gov.tw/AreaBus/libA/aa503.asp

The rules concern R&D and GMO products, and the activities of the cross-ministerial working group to date include the following: (1) the promulgation of the GMO Technology Management Bill[9]; (2) enhancing the legal hierarchy of the Lab Code of conduct of GM (基因重組實驗守則)[10]; (3) the establishment of an environment and ecological risk assessment and monitoring scheme; (4) the creation of the food safety evaluation, inspection, and certification system; and (5) conducting GMO product risk consultations and communications to improve public acceptance. Additionally, the cross-ministerial working group has also undertaken measures concerning the transparency of product info, in particular the labelling scheme.[11]

Food Safety

The Legal Definition of Food Safety

Currently, matters concerning food safety in Taiwan are governed by the Act Governing Food Safety and Sanitation ('the Food Act' or 'the Act').[12] Originally, the title of the Act did not include the words 'food safety' (i.e., the Act Governing Food Sanitation) and there is no legal definition for food safety in the Act although the concept of food safety is repeatedly mentioned through the Act. For instance, the stated purpose of the Act is to 'govern the food sanitation, safety and quality, and protect the health of citizens' (emphasis added).[13] The title of the Chapter II of the Act is provided as 'Chapter II Risk Management for Food Safety' (emphasis added).[14] Chapter III Sanitary Control of Food Businesses' also mentions the role of food safety; for example, 'Food businesses shall implement self-management to ensure food sanitation and safety' (emphasis added).[15]

Recently, in the aftermath of a series of scandals concerning the supply of toxic/chemical starch[16] and substandard food oils,[17] rice adulteration,[18] and deceptive advertising from an upmarket bakery,[19] the government initiated a wide range of

[9] The GMO Technology Management Bill of 2005, see: http://www.coa.gov.tw/show_communique.php?cat=show_communique&serial=9_webuser1_20050328095520

[10] The code, please see: http://www.nsc.gov.tw/bio/ct.asp?xItem=6202&ctNode=1267

[11] http://www.pabp.gov.tw/AreaBus/libA/aa503.asp

[12] Act Governing Food Safety and Sanitation, Amended Date 2015.02.04, available at: http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0040001

[13] Article 1 of the Food Act.

[14] Article 4–6 of the Food Act.

[15] Article 7(1) of the Food Act.

[16] http://www.taipeitimes.com/News/editorials/archives/2013/06/10/2003564407
http://www.taipeitimes.com/News/taiwan/archives/2013/05/28/2003563383

[17] http://www.taipeitimes.com/News/front/archives/2013/11/01/2003575875

[18] http://www.taipeitimes.com/News/taiwan/archives/2013/10/08/2003574010

[19] http://www.taipeitimes.com/News/taiwan/archives/2013/08/24/2003570479

measures for addressing food safety issues. The role of food safety, rather than the more traditional concept of sanitation, has received much more attention from the government. For example, during the amending of the Food Act in December 2013, certain members of the Taiwanese parliament stated that it seemed that 'sanitation' was not a major issue under the Food Act. They strongly recommended revising the title of the Food Act to the Act on Food Safety and Sanitation, and prioritising the issue of safety over that of sanitation.[20] In order to emphasize the importance of food safety, the Act was intensive amended in July 2013, February 2014, December 2014, and February 2015. Among the amendments, it is worth noting that the title of the Act was amended in February 5, 2014 to include the term "food safety."

The Political Context of Food Safety

A series of food scandals have been used by the political opposition to demonstrate the inability of the current government to deal with a critical everyday issue such as food safety. The food safety issue, combined with other issues such as low GDP growth, high unemployment rate, the rise of the anti-nuclear power movement, the death of a conscript after overtly harsh punishment,[21] and opposition to cross-strait free trade agreements including the ECFA[22] and service trade agreements,[23] have contributed to both a perception of government powerlessness and a shrinking approval rating for the ruling party, which is currently just 12.5 %.[24]

The Labelling of GMO Food

The food scandals referred to above are mostly related to the issue of food fraud, such as rice adulteration and deceptive advertising. However, they also concern the illegal use of prohibited materials in food, such as toxic starch and substandard food oil.

During the course of their investigations into the recent food scandals, the media also uncovered cases concerning the illegal use of industrial class soybeans (including those used for feeding cattle) for regular food purposes, such as making tofu, soybean milk, and soybean oil. It was discovered that of the total 2.3 million tonnes of soybeans being imported each year, only 20,000 tonnes is of an acceptable food grade quality and non-GMO; the remaining 2.28 million tonnes is GMO industrial-class soybeans.[25]

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[20] http://www.nownews.com/n/2013/12/09/1046912

[21] http://www.taipeitimes.com/News/front/archives/2013/07/21/2003567799

[22] http://www.taipeitimes.com/News/front/archives/2013/06/29/2003565909

[23] http://www.taipeitimes.com/News/front/archives/2013/06/23/2003565441

[24] President's approval rate hits new low http://www.taipeitimes.com/News/taiwan/archives/2013/11/14/2003576837

[25] http://www.ettoday.net/news/20130625/230955.htm

Although this concerned both GMO labelling and the grading of food, the news had the effect of drawing the attention of the general public towards the GMO food issue in mid-2013. Several consumer NGOs raised the issue again in December 2013 when the revision of the Food Act was being deliberated. In response, the Taiwan Food and Drug Administration (FDA, which is a subordinate agency under the MOHW) proposed an amendment to the Food Act to address such issue and such amendment was passed on February 5, 2014. In such amendment, it is specifically required that any foods that contain GMO food raw material should be labelled. However, relevant labelling details would be specified in the Labelling Ordinance to be promulgated by the FDA (please refer to sections "GMO food and food law", "Labelling requirement" and "The labelling regime" in this chapter).

Legal Superstructure: The Legal Superstructure for Genetic Technology and Food Safety Law

The constitutional law of Taiwan comprises three sections: basic human rights, the separation of powers and governmental design, and basic national policies. The concept of genetic technology can arguably come under the section concerning basic human rights, under the principle of research freedom enshrined by Article 11.[26] Similarly, Article 15, which concerns the right of living, surviving, and health, could be linked to food safety issues.[27] The section pertaining to the separation of powers and government design is less relevant to genetic technology and food safety. Lastly, a large number of provisions under the basic national policies could be of relevance to food safety issues.

Firstly, Article 146 expounds on the need for technology and R&D in the agricultural sector, and so it could have some implications for the development of agriculture relating GMO technology.[28] The requirement relating to the right to a minimum quantity of food could be a highly pertinent issue under Taiwan's social security policy.[29] In addition, the general R&D clause could be interpreted as being highly supportive of genetic technology R&D.[30] Finally, the clause on balancing the development of economic growth, technology development, and environmental

[26] Article 11 of the Constitution states: 'The people shall have freedom of speech, teaching, writing and publication'.

[27] Article 15 of the Constitution states: 'The right of existence, the right of work, and the right of property shall be guaranteed to the people'.

[28] Article 146 of the Constitution states: 'The State shall, by the use of scientific techniques, develop water conservancy, increase the productivity of land, improve agricultural conditions, plan for the utilization of land, develop agricultural resources and hasten the industrialization of agriculture'.

[29] Article 155 of the Constitution states: 'The State, in order to promote social welfare, shall establish a social insurance system. To the aged and the infirm who are unable to earn a living, and to victims of unusual calamities, the State shall give appropriate assistance and relief'.

[30] Article 166 of the Constitution states: 'The State shall encourage scientific discoveries and inventions'.

protection could be read as being closely associated with the concept of genetic technology and human health.[31]

Between the constitution and law, there is a unique 'Basic Law' regime in Taiwan. This kind of basic law or fundamental act serves as a type of policy act that gives policy and legal principles the status of law. For instance, a considerable number of technology development initiatives are funded by the MOST under the Fundamental Science and Technology Act,[32] as is true of research in the field of genetic technology. In addition, several provisions in the Environmental Basic Act[33] are related to generic technology research and human health, such as the purpose clause of Article 1,[34] the principle of environment value priority over technology,[35] the efforts in environmental R&D,[36] the efforts of maintaining biodiversity,[37] health

[31] Article 10 (2) of The Additional Articles of the Constitution of the Republic of China, as amended on 10 June 2005 states: 'Environmental and ecological protection shall be given equal consideration with economic and technological development'.

[32] Fundamental Science and Technology Act, as amended 14 December 2011.

[33] Environmental Basic Act, see: http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=O0100001

[34] Article 1 of the Act states:

This Act is formulated to raise the quality of the environment, advance the health and well-being of citizens, preserve environmental resources, and pursue sustainable development by promoting environmental protection. The regulations of other laws shall apply to those matters not regulated by this Act.

[35] Article 3 of the Act states:

Economic, technological and social development shall equally emphasize environmental protection based on long-term national interests. However, in the event that economic, technological or social development has a seriously negative impact on the environment or endangers the environment, the protection of the environment shall prevail.

[36] Article 8 of the Act states:

Government entities at all levels shall incorporate environment first and sustainable development concepts. They shall also develop related science and technology and establish economically efficient systems for environmental lifecycle management and green consumption to contend with issues related to the environment.

Additionally, Article 35 of the Act states:

The central government shall provide incentives for academic and research organizations involved in environmental protection to upgrade facilities, recruit and train personnel, introduce advanced technologies, and integrate research resources, hastening the development of demonstration projects and research on environmental protection technology.

[37] Article 18 of the Act states:

Government entities at all levels shall actively protect wildlife, ensure biodiversity, protect forests, estuaries and wetland environments, and maintain a diverse natural environment, while also enhancing water resource conservation, water and soil conservation, and revegetation and greenification work.

risk and environment,[38] the precautionary principle, and the monitoring duty of the government,[39] among other provisions.

Thus, from the perspective of Taiwan's legal superstructure, there is also a *middle* approach that could be found in terms of generic technology and food safety. On the one hand, the promotion of genetic technology could be legitimised by the doctrine or principle of R&D promotion. On the other hand, the need to taking into account issues such as human health, biodiversity, or other environmental risks are also mentioned in related laws. This can be shown from the following discussion, which examines the approach of relevant laws and detailed regulations.

Outline of the Relevant Law

The relationship between the legal regimes for GMO R&D and food products is illustrated in Fig. 12.1. As the focus of this article is on GMO food, this article will not discuss the GMO product regime.

Genetic Technology Law and RD&D

At the R&D phase, the relevant authorities would be the MOST and the AC. The MOST develops rules that tend to be more general than those developed by the AC; two examples would be the Lab Code of Conduct of GM[40] and the GM Experiment Consent.[41] As noted above, the GM technology will apply mainly to GMO plants, GMO animals, and aquaculture crops and livestock. Thus, the AC has authority over the development and implementation of the regulatory regime on more complex RD&D projects.

For GMO plants, the legal basis for an administrative ordinance relating to GMO (The Ordinance on the Management of GM Plants in Field Experiments (基因轉植物田間試驗管理辦法)) is found in Article 52(3) of the Plant Variety and Plant

[38] Article 22 of the Act states: 'Government entities at all levels shall actively conduct research and establish environmental and health risk assessment systems, adopt preventive and medical healthcare measures, reduce health risks, and prevent or lessen diseases related to the environment'.

[39] Article 27 of the Act states: 'Government entities at all levels shall establish a strict environmental monitoring network, regularly publish monitoring results, establish pre-warning systems, and adopt necessary measures'.

[40] Lab Code of Conduct of GM (基因重組實驗守則), available at: www.nsc.gov.tw/SCI/public/Attachment/691415403671.doc

[41] GM Experiment Consent (「基因重組實驗申請同意書」), available at: http://www.nsc.gov.tw/bio/public/Attachment/691415405071.doc

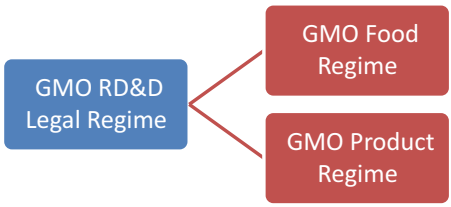

Fig. 12.1 The relationship between the legal regimes for GMO R&D and food products

Seed Act.[42] In turn, the Ordinance of the Management of GM Animals in Field Experiments (基因轉殖種畜禽田間試驗及生物安全性評估管理辦法) and the Ordinance of the Management of GM Aquaculture Livestock in Field Experiments (基因轉殖水產動植物田間試驗管理規則) are based on the Animal Industry Act[43] and the Fisheries Act,[44] respectively. The detailed regime will be elaborated upon in Sect. "Restriction of GMO: RD&D phase" of this article. It suffices to mention here that there are many common points among these regulations.

[42] Article 52 of The Plant Variety and Plant Seed Act states:

Without the approval of the central competent authority, the importation or exportation of transgenic plants is prohibited. The regulations governing approval for the importation or exportation of transgenic plants shall be prescribed by the central competent authority.

Unless the applicant has obtained approval from the central competent authority to conduct field testing, has passed the field examination, and has submitted the documentation of the approval as issued by the central competent authority concerning the main purposes as declared in the application, a transgenic plant imported from abroad or bred domestically is prohibited from domestic promotion or sale.

The testing methods, application and examination procedures, relevant administrative regulations, and the standard rates of the testing fees of the field testing referred to in the preceding Paragraph shall be prescribed by the central competent authority. [emphasis added].

[43] Article 12—1 of the Animal Industry Act states:

Breeding flock or breeding stock involving the transfer of genetic material shall undergo field tests and creatures' safety assessment before it can be promoted and made use of. The regulation measures on the transfer of genetic material will be set forth by the central competent authority. [emphasis added].

[44] Article 69 of the Fisheries Act states:

The regulations for registration and management of inland aquaculture shall be prescribed by the municipal/county/city competent authority.

The municipal/county/city competent authority may plan and set up an aquaculture production area in which the environment is appropriate for developing aquaculture or presently fish farms concentrated. The regulations for the establishment and management shall be prescribed by the central competent authority.

Any aquatic organisms that involved in genetic breeding and transference shall run prior field tests and safety assessments before promotion and utilization. The regulations on the field test and breeding management of genetic bred and transferred aquatic organisms shall be prescribed by the central competent authority. [emphasis added].

GMO Food and Food Law

The division of regulatory responsibility among different authorities can also be attributed to the function of different laws. Before their entry into the food chain, crops, animals, and aquaculture crops and livestock are subject primarily to the regulatory regime and the authority of the agriculture sector; thus, the dominant role of the AC at the RD&D phase can be observed.

However, after the RD&D phase, the GM plants, animals, and aquaculture livestock would be considered safe for eating or selling on the market for other non-eating purposes. At that stage, different authorities come into play.

In relation to areas concerning food purpose and food authorship, the MOHW are in charge of the approval of GM food. Currently effective rules are all concerning soybean and corn, such as the Ordinance on the Announcement of Mandatory Registration and Permission Duty of Corn and Soybean (「基因改造之黃豆及玉米」應向中央主管機關辦理查驗登記), the Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn (GM Soybean and Corn Labelling Ordinance;以基因改造黃豆及基因改造玉米為原料之食品標示事宜),[45] and the Ordinance of Safety Evaluation Method for GM Food (基因改造食品安全性評估方法). However, it has been announced by the MOHW on December 22, 2014 that the GM Soybean and Corn Labelling Ordinance will become abolished on January 1, 2016, [46] and that three general Labelling Ordinances (Ordinance on the Labelling of Packaged Food Containing GM Food Raw Materials (包裝食品含基因改造食品原料標示應遵行事項); Ordinance on the Labelling of Food Additives Containing GM Food Raw Materials (食品添加物含基因改造食品原料標示應遵行事項); and Ordinance on the Labelling of Bulk Food Containing GM Food Raw Materials (散裝食品含基因改造食品原料標示應遵行事項)) promulgated through the same announcement will become effective as of January 1, 2016.[47]

GM plants, animals, and aquaculture livestock could be also used for other leisure purposes, cultivation, or mass production purposes. As such, an approval scheme has also been established for GM plants,[48] animals,[49] and aquaculture crops and livestock.[50] However, this GM product approval scheme will not be the focus of the present article.

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[45] Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn (以基因改造黃豆及基因改造玉米為原料之食品標示事宜), Enacted on 22 February 2001, Recent Revision on 26 September 2013.(中華民國90年2月22日衛署食字第0900011746號公告,中華民國102年9月26日部授食字第1021350529號公告修正).

[46] http://gazette.nat.gov.tw/EG_FileManager/eguploadpub/eg020244/ch08/type1/gov70/num20/Eg.htm

[47] http://gazette.nat.gov.tw/EG_FileManager/eguploadpub/eg020245/ch08/type1/gov70/num28/Eg.htm

[48] Article 52(2) of the Plant Variety and Plant Seed Act.

[49] Article 3, the Ordinance of the Management of GM Animals in Field Experiments.

[50] Article 27 and 28, Ordinance of the Management of GM Aquaculture crops and livestock in Field Experiments.

Admission

Restriction of GMO: RD&D Phase

There is no general prohibition against GMO in Taiwan. However, in order to conduct GMO R&D, there are certain rules in place for the approval of RD&D initiatives or projects that must be observed.

As noted above, at the R&D phase, the main authorities are the MOST and the AC. The MOST's regulation on genetic technology through the Lab Code of conduct of GM[51] is more general than those rules developed by the AC. This Lab Code is applied to all GM technologies and is implemented and supervised by the 'Biological Experiments Safety Commission (生物實驗安全委員會)' of each university and research institute. Any GM-related research projects are required to obtain the GM Experiment Consent[52] and present its research proposal when doing so.[53]

The AC is in charge of the further RD&D of GM plants, animal, and aquaculture crops and livestock. The detailed regulation through three key ordinances (the Ordinance on the Management of GM Plants in Field Experiments (基因轉植物田間試驗管理辦法), the Ordinance of the Management of GM Animals in Field Experiments (基因轉殖種畜禽田間試驗及生物安全性評估管理辦法), the Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments (基因轉殖水產動植物田間試驗管理規則) will be elaborated on below.

The Establishment of Isolated Experimental Fields

With a view to preventing pollution and contamination from GM experiments, the establishment of isolated experimental fields is the first priority in the aforementioned management ordinances.

The Research Institute of Agriculture (RIC) of the AC (農委會農業試驗所) is developing a national isolated facility for GMO crop and plant experiments. The Hsinchu branch of the RIC and the Marine Water Cultivation Centre (the Experiment Institute of Aquaculture Livestock of AC) (農委會水產試驗所海水繁養殖研究中心) construct isolated experiment fields for GMO animals, and aquaculture crops and livestock.[54]

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[51] Lab Code of conduct of GM (基因重組實驗守則), available at: www.nsc.gov.tw/SCI/public/Attachment/691415403671.doc

[52] GM Experiment Consent(「基因重組實驗申請同意書」), available at: http://www.nsc.gov.tw/bio/public/Attachment/6914154050 71.doc

[53] http://www.nsc.gov.tw/bio/ct.asp?xItem=6202&ctNode=1267

[54] http://www.pabp.gov.tw/AreaBus/libA/aa503.asp

Qualified Institute

The field experiments of GMO plants should be conducted by a research institute approved by the AC.[55] The eligibility conditions of such research institutes include having professional facilities such as airtight greenhouses, half-airtight greenhouses, and isolated farms[56]; staff[57]; and a code of conduct.[58] A similar regime is also applied to institutes researching aquaculture livestock and crops,[59] and to these institutes the requirements relating to professional facilities, professional staff, and work to a code of conduct are also applicable.[60]

There is no such requirement for research into GM animals. A more substantial requirement, discussed below, applies to these research initiatives.

Field Experiments and Biosafety Assessment (田間試驗、生物安全性評估)

Plants Field experiments in the area of GMO crop research are reviewed by the Review Commission on GM plants.[61] Field experiments and biosafety assessment is governed by the Chapter III of the Ordinance.[62]

Animals The experiment and biosafety assessment of GM animals are reviewed by the Review Taskforce on GM Livestock.[63] Biosafety assessment is regulated by Article 4 of the Ordinance.

Aquatic Living Field experiments of GM aquaculture crops and livestock are reviewable by the Review Commission on GM Aquaculture Crops and Animals.[64] The detailed regulations on field experiments and biosafety assessments are regulated by Chapter III of the Ordinance.

Licensing of GMO Imports and Exports

Following the Cartagena Protocol on Biosafety, Taiwan set up export and import regulation for GMO products.

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[55] Article 3 of the Ordinance on the Management of GM Plants in Field Experiments.

[56] Article 10, 11 of the Ordinance on the Management of GM Plants in Field Experiments.

[57] Article 12 of the Ordinance on the Management of GM Plants in Field Experiments.

[58] Article 13, the Ordinance on the Management of GM Plants in Field Experiments.

[59] Article 3 of Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments.

[60] Article 6, 8, 10 of the Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments.

[61] Article 4 the Ordinance of the Management of GM Plants in Field Experiments.

[62] The Ordinance on the Management of GM Plants in Field Experiments.

[63] Article 5 the Ordinance of the Management of GM Animals in Field Experiments.

[64] Article 4 the Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments; Ordinance on Review Commission of GM Aquaculture Crops and Livestock.

Plants The export and import of GM plants for R&D or cultivation purposes must be subject to the approval of the AC.[65] The Ordinance on Export and Import of GM Plants provides detailed regulations on this matter.[66]

In general, a similar license is also required for GM livestock.[67] Yet, if the sole purpose is R&D and experimental applications, there is an exemption on the biosafety assessment and field experiment requirement during the permission process.[68]

For GM aquaculture crops and livestock, the same licensing regime of export and import applies.[69]

Long-Term Monitoring and Inspection (追蹤監測)

In order to address the environmental, health, and safety concerns associated with GM plants, animals, and aquaculture crops and livestock livings, both ex ante and ex post approaches to regulation are necessary. To complement the ex ante regulation highlight above, the ex post, long-term monitoring scheme has been established through the Ordinance on the Management of GM Plants in Field Experiments[70] and the Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments.[71] The scheme is quite similar: the AC authorises a professional institute to monitor the safety of GM plants and aquaculture crops and livestock.

However, this scheme is missing from the earlier Ordinance on GM Livestock.[72] Despite this, in practice, the AC's research centre conducts the long-term inspection and monitoring scheme for crops such as rice, papaya, and potato.[73]

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[65] Article 52(1) of the Plant Variety and Plant Seed Act.

[66] The Ordinance on the Export and Import of GM Plants. (基因轉殖植物輸出入許可辦法), available at: http://www.coa.gov.tw/view.php?catid=9812

[67] Article 19 of The Animal Industry Act states: 'Breeding flock or breeding stock that have been designated by the central competent authority shall obtain the approval document of the same authority before it can be imported or exported'.

Please see also, Ordinance on the Permission and Review of Importing Animals (種畜禽及種原輸入同意文件審核要點) and Ordinance on the Permission and Review of Exporting Animals (種畜禽及種原輸出同意文件審核要點).

[68] Article 3II, the Ordinance of the Management of GM Animals in Field Experiments.

[69] Article 15, 16, 17, Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments.

[70] Article 33, the Ordinance on the Management of GM Plants in Field Experiments.

[71] Article 29, the Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments.

[72] The Ordinance on GM Animals was promulgated in 15 November 2002, which is much earlier than the other two Ordinances, which were promulgated in after 2011.

[73] http://www.pabp.gov.tw/AreaBus/libA/aa503.asp

Admission of GMO in Food Production

Currently, only soybean and corn are admitted in food production under Taiwan's GMO regulatory framework. The regulations concerning the admission of GMO into food production and procedures for admission are as follows.

R&D to Food

The question of which authorities are empowered to regulate the stages between the R&D phase and food production phase is made clear by the regulations. Even in the GM R&D regulations, all ordinances recognise the power of the FDA to regulate issues concerning the consumption of GM livestock,[74] GM aquaculture crops and livestock,[75] and GM plants and crops.[76] Thus, the question of whether certain R&D 'materials' can be classified as edible food rests on Taiwan's central food authority, the FDA.

Registration and Permission

Even though there are potential GM foods currently in development, the regulatory focus of the relevant food law is mainly on the import of GM soybean and corn.

On 11 February 2001, under the authorization of the Food Act, the Ordinance on the Announcement of Mandatory Registration and Permission Duty of Corn and Soybean (「基因改造之黃豆及玉米」應向中央主管機關辦理查驗登記) was promulgated. Originally, the scheme was intended to apply to GM papaya, potato, tomato, and rice only between January to July of 2004 under the Draft Ordinance of Registration and Permission of GM Food.[77] However, to date, only soybean and corn have fallen under such a duty. The reason is probably related to the fact that all soybean and corn in Taiwan are imported and face less opposition from local famers.

The permission process requires the production of key document: the GM Food Safety Assessment Report.[78] Any related research papers and articles can be attached to this report to be reviewed, and a payment for the reviewing process is required.[79]

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[74] Article 7, the Ordinance of the Management of GM Animals in Field Experiments.

[75] Article 27, Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments.

[76] Article 52(2) of the Plant Variety and Plant Seed Act.

[77] http://www.gmp.org.tw/newsdetail.asp?id=1674

[78] Article 2 of the Ordinance on the Announcement of Mandatory Registration and Permission Duty of Corn and Soybean.

[79] Ordinance on the Fee and Payment for Registration and Permission of Importing Food and related Products (輸入食品及相關產品查驗規費收費標準).

For instance, the fee for the Ordinary Quantitative Test for GM soybean and corn (single transgenic) is NT$17,900; the fee for the Qualitative test is NT$12,000.[80]

The approved GMO food list is reproduced in Table 12.1 and Table 12.2 below. Table 12.3 lists discontinued foods or foods with expired approvals.[81]

Labelling Requirement

The Taiwanese government has established a labelling scheme to complement the registration and permission scheme. On 22 February 2012, the Ordinance on the Labelling of Food Whose Source is GM Soybean and Corn came into force,[82] which will become abolished on January 1, 2016, and be replaced by three general Labelling Ordinances that will become effective on the same day.[83] The labelling regime will be discussed in detail in section "Labelling".

Safety Evaluation

On the issues of regulations pertaining to the safety issue of GM food, it is useful to note that the MOHW promulgated the Ordinance of Safety Evaluation Method for GM Food (基因改造食品安全性評估方法) on 20 August 2008, which was amended on 9 September 2010. The legal basis for this regulation is Article 14 of the Food Act (version effective in 2010).[84]

This ordinance is applicable to those who intend to produce or import GM food. Under the Ordinance, the party should notify the MOHW and ensure full compliance with the Ordinance.[85]

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[80] Annex Table of Ordinance on the Fee and Payment for Registration and Permission of Importing Food and related Products.

[81] Current Approvals of Genetically Modified foods in Taiwan-20111216, available at: https://consumer.fda.gov.tw/Files/PageFile/506_6500/Current%20Approvals%20of%20Genetically%20Modified%20foods%20in%20Taiwan-20111216.doc

[82] Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn (以基因改造黃豆及基因改造玉米為原料之食品標示事宜), Enacted on 22 February 2001, Recent Revision on 26 September 2013.(中華民國90年2月22日衛署食字第0900011746號公告,中華民國102年9月26日部授食字第1021350529號公告修正).

[83] See above notes 47 and 48.

[84] Article 14 of the Act Governing Food Sanitation Article 14 states: 'The regulations governing the sanitation of public food and beverage sites shall be prescribed by the municipal or county/city competent authority based on the various sanitation standards or laws promulgated by the central competent authority'. Please see also Article 32 of the Ordinance on the Management of GM Plants in Field Experiments.

[85] Article 2 of the Ordinance of Safety Evaluation Method for GM Food. (本評估方法針對利用『基因改造技術』生產的食品(以下統稱『基因改造食品』),訂定其安全性評估所要考量之基本要件,以消除消費者疑慮,確保民眾飲食的安全。欲製造或輸入『基因改造食品』者,應向衛生主管機關申報,以確認產品符合本評估方法之要求。).

Table 12.1 Current approved products – single trait

	Unique identifier	Product	Name	Event	Applicant	Date of approval	Date of expiration
1	MON-Ø4Ø32-6	Soybean	Glyphosate tolerant Roundup Ready Soybean	40-3-2 (RRS)	Monsanto Far East Ltd., Taiwan Branch	July 22, 2002	July 22, 2012
2	MON-ØØ81Ø-6	Corn	Insect-resistant YieldGard Corn	MON810	Monsanto Far East Ltd., Taiwan Branch	October 15, 2002	October 15, 2012
3	MON-ØØ6Ø3-6	Corn	Glyphosate tolerant Roundup Ready Corn	NK603	Monsanto Far East Ltd., Taiwan Branch	April 11, 2003	April 11, 2013
4	SYN-BTØ11-1	Corn	Insect-resistant & Glufosinate tolerant Corn	Bt11	Syngenta Taiwan Ltd.	June 2, 2004	June 2, 2013
5	SYN-EV176-9	Corn	Insect-resistant & Glufosinate tolerant Corn	Event176	Syngenta Taiwan Ltd.	June 2, 2004	June 2, 2013
6	ACS-ZMØØ3-2	Corn	Glufosinate tolerant Corn	T25	Bayer Taiwan Ltd.	August 16, 2002	August 16, 2012
7	DAS-Ø15Ø7-1	Corn	Insect-resistant & Glufosinate tolerant Corn	TC1507	DuPont Taiwan	November 17, 2003	November 17, 2013
8	MON-ØØ863-5	Corn	Insect-resistant, YieldGard Rootworm Corn	MON863	Monsanto Far East Ltd., Taiwan Branch	October 16, 2003	October 16, 2013
9	DAS-59122-7	Corn	Insect-resistant & Glufosinate tolerant Corn	59122	DuPont Taiwan	December 21, 2005	December 21, 2015
10	MON-88Ø17-3	Corn	YieldGard Rootworm/ Roundup Ready Corn	MON88017	Monsanto Far East Ltd., Taiwan Branch	March 20, 2006	March 20, 2016
11	ACS-GMØØ5-3	Soybean	Glufosinate tolerant Soybean	A2704-12	Bayer Taiwan Ltd.	May 1, 2007	May 1, 2012
12	SYN-IR6Ø4-5	Corn	Insect-resistant Corn	MIR604	Syngenta Taiwan Ltd.	October 22, 2007	October 22, 2012

13	MON-89788-1	Soybean	Roundup RReady2Yield Soybean	MON89788	Monsanto Far East Ltd., Taiwan Branch	December 28, 2007	December 28, 2012
14	MON-ØØØ21-9	Corn	Glyphosate tolerant Corn	GA21	Syngenta Taiwan Ltd.	July 23, 2008	July 23, 2013
15	MON-89Ø34-3	Corn	Insect-resistant Corn	MON89034	Monsanto Far East Ltd., Taiwan Branch	July 25, 2008	July 25, 2013
16	SYN-IR162-4	Corn	Insect-resistant Corn	MIR162	Syngenta Taiwan Ltd.	Apr 20, 2009	Apr 20, 2014
17	DP-356Ø43-5	Soybean	Glyphosate and Acetolactate Synthase (ALS)-Inhibiting Herbicides Tolerant Soybean	DP-356043-5	DuPont Taiwan Ltd.	May 11, 2009	May 11, 2014
18	DP-3Ø5423-1	Soybean	High Oleic Soybean	DP-305423-1	DuPont Taiwan Ltd.	July 23, 2010	July 23, 2015
19	SYN-E3272-5	Corn	α-Amylase Corn	Event 3272	Syngenta Taiwan Ltd.	Jul 26, 2010	July 26, 2015
20	ACS-GMØØ6-4	Soybean	Glufosinate tolerant Soybean	A5547-127	Bayer Taiwan Ltd.	Aug 31, 2010	Aug 31, 2015
21	MON-877Ø1-2	Soybean	Insect-Protected Soybean	MON87701	Monsanto Far East Ltd., Taiwan Branch	July 6, 2011	July 6, 2016
22	MON-8746Ø-4	Corn	Drought Tolerant Corn	MON87460	Monsanto Far East Ltd., Taiwan Branch	November 3, 2011	November 3, 2016
23	DAS-4Ø278-9	Corn	DAS-40278-9 Corn	DAS-40278-9	Dow AgroSciences Taiwan Ltd.	November 7, 2011	November 7, 2016

Table 12.2 Current approved products – stacked trait

	Unique identifier	Product	Name	Event	Applicant	Date of approval	Date of expiration
1	MON-89Ø34-3 x MON-88Ø17-3	Corn	YieldGard VT Triple PRO Corn	MON89034 x MON88017	Monsanto Far East Ltd., Taiwan Branch	February 17, 2009	February 17, 2014
2	MON-89Ø34-3 x MON-ØØ6Ø3-6	Corn	YieldGard VT PRO x Roundup Ready Corn 2	MON89034 x NK603	Monsanto Far East Ltd., Taiwan Branch	February 17, 2009	February 17, 2014
3	MON-88Ø17-3 x MON-ØØ81Ø-6	Corn	YieldGard VT Triple Corn	MON88017 x MON810	Monsanto Far East Ltd., Taiwan Branch	February 17, 2009	February 17, 2014
4	MON-ØØ81Ø-6 x MON-ØØ6Ø3-6	Corn	YieldGard x Roundup Ready Corn 2	MON810 x NK603	Monsanto Far East Ltd., Taiwan Branch	February 17, 2009	February 17, 2014
5	MON-ØØ863-5 x MON-ØØ81Ø-6x MONØØ6Ø3-6	Corn	YieldGard Plus x Roundup Ready Corn 2	MON863 x MON810 x NK603	Monsanto Far East Ltd., Taiwan Branch	March 04, 2009	March 04, 2014
6	MON-ØØ863-5 x MONØØ6Ø3-6	Corn	YieldGard Rootworm x Roundup Ready Corn 2	MON863 x NK603	Monsanto Far East Ltd., Taiwan Branch	May 25, 2009	May 25, 2014
7	MON-ØØ863-5 x MON-ØØ81Ø-6	Corn	YieldGard Plus Corn	MON863 x MON810	Monsanto Far East Ltd., Taiwan Branch	July10, 2009	July10, 2014
8	SYN-BT011-1 x SYN-IR604-5	Corn	Bt11 x MIR604 maize	Bt11 x MIR604	Syngenta Taiwan Ltd.	August 3, 2009	August 3, 2014
9	SYN-BT011-1 x MON-ØØØ21-9	Corn	Bt11 x GA21 maize	Bt11 x GA21	Syngenta Taiwan Ltd.	August 3, 2009	August 3, 2014
10	SYN-IR604-5 x MON-ØØØ21-9	Corn	MIR604 x GA21 maize	MIR604 x GA21	Syngenta Taiwan Ltd.	August 3, 2009	August 3, 2014
11	SYN-BT011-1 x SYN-IR604-5 x MON-ØØØ21-9	Corn	Bt11 x MIR604 x GA21 maize	Bt11 x MIR604 x GA21	Syngenta Taiwan Ltd.	August 3, 2009	August 3, 2014

12	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	Corn	MON89034 x TC1507 x MON88017 x DAS-59122-7 Corn	MON89034 x TC1507 x MON88017 x DAS-59122-7	Monsanto Far East Ltd., Taiwan Branch	October 12, 2009	October 12, 2014
13	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	Corn	MON89034 x TC1507 x MON88017 x DAS-59122-7 Corn	MON89034 x TC1507 x MON88017 x DAS-59122-7	Dow AgroSciences Taiwan Ltd.	October 12, 2009	October 12, 2014
14	DAS-Ø15Ø7-1 x MON-ØØ603-6	Corn	TC1507xDAS -59122-7 Maize	TC1507 x DAS-59122-7	DuPont Taiwan Ltd.	December 02, 2009	December 12, 2014
15	DAS-Ø15Ø7-1 xDAS-59122-7	Corn	TC1507xNK603 Maize	TC1507xNK603	DuPont Taiwan Ltd.	December 15, 2009	December 15, 2014
16	DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØ603-6	Corn	DAS-59122xTC1507 xNK603 Maize	DAS-59122 xTC1507xNK603	DuPont Taiwan Ltd.	December 15, 2009	December 15, 2014
17	DAS-59122-7xMON-ØØ603-6	Corn	DAS-59122 xNK603 Maize	DAS-59122xNK603	DuPont Taiwan Ltd.	Jan 3, 2011	Jan 3, 2016
18	MON-ØØ6Ø3-6 x ACS-ZMØØ3-2	Corn	NK603xT25	NK603xT25	Monsanto Far East Ltd., Taiwan Branch	May 30, 2011	May 30, 2016
19	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6	Corn	TC1507xDAS-59122-7 x MON810xNK603	TC1507xDAS-59122-7 x MON810xNK603	DuPont Taiwan Ltd.	May 30, 2011	May 30, 2016

Table 12.2 (continued)

	Unique identifier	Product	Name	Event	Applicant	Date of approval	Date of expiration
20	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6	Corn	TC1507xMON810 xNK603	TC1507 xMON810xNK603	DuPont Taiwan Ltd.	May 30, 2011	May 30, 2016
21	SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON- ØØØ21-9	Corn	Bt11xMIR162 xMIR604xGA21	Bt11xMIR162 xMIR604xGA21	Syngenta Taiwan Ltd.	May 30, 2011	May 30, 2016
22	SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9	Corn	Bt11xMIR162xGA21	Bt11xMIR162xGA21	Syngenta Taiwan Ltd.	May 30, 2011	May 30, 2016
23	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6	Corn	MON89034 xTC1507xNK603	MON89034 xTC1507xNK603	Dow AgroSciences Taiwan Ltd.; Monsanto Far East Ltd., Taiwan Branch	August 22, 2011	August 22, 2016
24	SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9	Corn	3272xBt11 xMIR604xGA21	3272xBt11 xMIR604xGA21	Syngenta Taiwan Ltd.	September 5, 2011	September 5, 2016
25	SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9	Corn	Bt11xMIR162 xTC1507xGA21	Bt11xMIR162 xTC1507xGA21	Syngenta Taiwan Ltd.	October 14, 2011	October 14, 2016
26	DAS-Ø15Ø7-1 x SYN-IR6Ø4-5 x MON-ØØ6Ø3-6	Corn	TC1507xMIR604 xNK603 Maize	TC1507 xMIR604xNK603	DuPont Taiwan Ltd.	December 1, 2011	December 1, 2016

Table 12.3 Discontinued products or expiry of approval

	Unique identifier	Product	Name	Event	Applicant	Date of approval	Date of expiration
1	MON-ØØØ21-9	Corn	Glyphosate tolerant Roundup Ready Corn	GA21	Monsanto Far East Ltd., Taiwan Branch	July 22, 2003	July 22, 2008
2	DKB-89614-9	Corn	Insect-resistant & Glufosinate tolerant Corn	DBT418	Monsanto Far East Ltd., Taiwan Branch	October 16, 2003	October 16, 2008
3	DKB-8979Ø-5	Corn	Glufosinate tolerant Corn	DLL25	Monsanto Far East Ltd., Taiwan Branch	October 20, 2003	October 20, 2008
4	REN-ØØØ38-3	Corn	Lysine Maize	LY038	Monsanto Far East Ltd., Taiwan Branch	November 20, 2006	November 20, 2011

Further regulations have been developed for GM food,[86] GM plant food,[87] and GM microorganisms.[88] In general, the first-phase evaluation focuses on the evaluation of the data. If the results show the GM food has potential toxic materials or allergic material, then the second-phase evaluation is triggered. The second-stage evaluation follows the procedure laid out in Annex III (toxic materials) and Annex IV (allergic materials) to proceed with the evaluation. However, if the second stage is unlikely to provide answers on the safety of consuming the produce being tested, the third-phase evaluation is triggered, which would involve animal tests.

Threshold Limits

There are no limitation thresholds for GMO in food in Taiwan. Yet, as noted above, currently there is a threshold (5 %) for triggering the mandatory labelling requirement. If the GMO ingredient exceeds 5 % in the product, the food must be labelled as 'GM'. Such limitation threshold will be adjusted to 3 % as of January 1, 2016.[89]

[86] Chapter 2, Safety Evaluation of GM Food, Ordinance of Safety Evaluation Method for GM Food.

[87] Chapter 3, safety evaluation of GM Plant Food, Ordinance of Safety Evaluation Method for GM Food.

[88] Chapter 4, Safety Evaluation of GM Microorganism, Ordinance of Safety Evaluation Method for GM Food.

[89] See above notes 47 and 48.

Implementation and Enforcement, and the Controlling Regime

The implementation of the above regime relies on an expert review commission as well as regular monitoring and inspection of food-related professional institutes. At the RD&D phase, the expert commission has chief responsibility for reviewing GM-related experiments.[90] Qualified institutes would then play the key enforcement role during the implementation of experiments.[91] With respect to monitoring, inspecting, and tracking, the government is empowered to designate an institute capable of conducting inspection and monitoring to perform this role.[92] This process is evidence of the inability of the government to deal with the issue of implementation process, and it suggests the outsourcing to institutes and those with professional expertise is necessary to ensure the holistic and synchronistic implementation of the related laws and regulations.

At the food phase, the regulatory process is similar. Many experts and institutes would be likely to be involved in the process of permission and safety evaluation, and monitoring. In sum, these measures can be seen as part of the institutional design aimed at ensuring a first front line and layer of compliance in the larger regulatory and controlling scheme.

The ex post administrative penalty or criminal offense could have an effective role to play ensuring compliance. This point will be elaborated upon in section "Genetic technology and the R&D phase: public and criminal law".

The Labelling Regime

Labelling

A labelling scheme is also in place to complement the registration and permission scheme, i.e., GM Soybean and Corn Labelling Ordinance.[93]

A mandatory labelling scheme for GM or 'GM included' produce applies to products that contain GM soybean and corn. The requirement for labelling applies when the weight of the GM ingredients is equal to or greater than 5 % of the total

[90] For example, please see Article 5, Ordinance of the Management of GM Animals in Field Experiments.

[91] For example, please see Article 3, the Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments.

[92] For example, please see Article 29, the Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments.

[93] See above note 46.

weight of the food product.[94] The label must be affixed on a prominent place on the product and the font size and the width should not be less than 2 mm.[95]

Different products are subject to different starting phases. Since 1 January 2003, labelling requirements have applied to agricultural products derived from soybean and corn, including soybeans, soybean meal, corn, and crushed corn (powder). Since 1 January 2004, labelling requirements have applied to primary processed food that use soybean and corn as core raw materials, such as tofu, tofu, soy milk, tofu, frozen corn, canned corn, and soy protein products. Since 1 January 2005, labelling requirements have applied to other highly processed food with soybean and corn.[96] However, an exemption scheme has been provided for the use of GM soybean or corn in the production of soy sauce, soybean oil (vegetable oil), corn oil, corn syrup, and corn starch.[97]

A voluntary labelling scheme of 'non-GM' products applies to those products using non-GM soybean or corn as a raw material.[98] This scheme applies retrospectively from 1 January of 2001.[99] Food products that are the result of the unintentional mixing of GM soybean or corn totalling less than 5 % during the cultivation or storage process would be considered as non-GM.[100]

In addition, there is a mandatory labelling and packaging scheme in effect that concerns GM plants used in export, import, transport, sales, or promotion.[101] The Ordinance of Packaging and Labelling for GM Plants provides further regulations on this issue. Before marketing and sale, the party seeking to sell must first apply for a code.[102] Under the Ordinance, this code has to be displayed along with other 12 items on the label. These items include the distinct and clear printing of the word 'GM', the country of production, the features of the GM plants, the purpose of the GM plants, the preservation and transportation condition of the GM plants, safety handling procedures for emergencies, and more.[103] The format of the label is also regulated. For instance, a Chinese translation is mandated and the font length and

[94] Article 1 of the Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[95] Article 5, the Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[96] Article 6, the Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[97] Article 4 and 6(3) of the Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[98] Article 2, the Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[99] Article 7, the Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[100] Article 3, the Ordinance on the Labelling of Food Whose Source is From GM Soybean and Corn.

[101] Article 54(4) of the Plant Variety and Plant Seed Act states: Due to food safety and environmental safety, transgenic plants shall be appropriately packaged and labelled for import, export, transport, marketing, and sale. The packaging and labelling regulations shall be prescribed by the central competent authority'.

[102] Article 2 of the Ordinance of Packaging and labelling for GM Plants (基因轉殖植物之標示及包裝準則).

[103] Article 3, the Ordinance of Packaging and labelling for GM Plants.

width cannot be smaller than 0.4 cm.[104] With regard to packaging, according to Article 6 of the Ordinance, seeds of GM plants should be packed compactly. When transporting, exporting, or importing GM plants, there is a requirement to pack GM plants firmly, ensuring that the package is not easily broken and the materials not easily scattered.[105]

As mentioned above, it has been announced by the MOHW on December 22, 2014 that the GM Soybean and Corn Labelling Ordinance will become abolished on January 1, 2016, and that three general Labelling Ordinances will become effective as of January 1, 2016.[106] These three general Labelling Ordinances will be applicable to all GM food, but not limited to soybean and corn products. In addition, the threshold (5 %) for triggering the mandatory labelling requirement under the GM Soybean and Corn Labelling Ordinance will be adjusted to 3 % as of January 1, 2016 pursuant to these three general Labelling Ordinances.

Legislation Addressing Labelling Fraud

Labelling Fraud in the Food Industry

If a food business operator fails to label GM factors as required by the Food Act, such operator shall be fined between NT$30,000 and NT$3,000,000. In severe circumstances, the operator may be ordered to terminate business, suspend business for a certain period of time, revoke all or part of the items listed in the company registration, business registration or factory registration, or registration of the food businesses. If registration of the food businesses is revoked, re-application for new registration shall not be permitted within one year.[107]

Article 24 of the Consumer Protection Act imposes a duty to label all food products.[108]

> Business operators shall label on the products or for services in accordance with the *Products Labelling Act* and other relevant laws and regulations.
>
> Imported goods or services shall be accompanied with labels and instructions in Chinese, the contents of which shall not be less comprehensive than the contents of such labels or pamphlets required in the place of their origin.
>
> If imported goods or services at the place of their origin are accompanied with warning labels, the preceding paragraph shall apply mutatis mutandis.

The Article 9 of Products Labelling Act provides additional requirements for the information to be included on labels:

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[104] Article 4, the Ordinance of Packaging and labelling for GM Plants.

[105] Article 7, the Ordinance of Packaging and labelling for GM Plants.

[106] See above notes 46–48.

[107] Articles 47 and 48 of the Food Act (currently effective version).

[108] The Consumer Protection Act, available at: http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=J0170001

Where a commodity is introduced for sale on the market, the following particulars shall be labelled for the commodity by the producer, manufacturer or importer of such commodity:

1. Name of the commodity;
2. Name, telephone number and address of the producer or manufacturer, the place of origin of the commodity, and the name, telephone number and address of the importer in the case of imported commodity;
3. Contents or composition of the commodity:
   (1) Major components/ingredients or materials;
   (2) Net weight, volume or quantity, or measurements which shall be labelled in statutory measuring units, other measurements may be added, when it is deemed necessary;
4. Date of manufacture in Chinese calendar or Gregorian calendar; and the expiration date or the term of validity, if the commodity has a limited duration of storage; and
5. Other particulars as required by the central government competent authority.

An administrative fine or penalty may be imposed in the event of non-compliance with labelling requirements. Acts of non-compliance include labelling fraud. Provisions relating to fines and penalties exist under both the Consumer Protection Act[109] and the Products Labelling Act.[110]

The above regime applies to all products, but for food products, the Act Governing Food Sanitation prevails over both the Consumer Protection Act and Products Labelling Act. Thus, if there is a labelling fraud, the Act Governing Food Sanitation provides that a notice shall be given for the goods to be recalled and correction made within a prescribed time period, and the goods in question shall not be sold before the violation is corrected. In case the notice is not complied with within the prescribed

[109] Article 56 of the Consumer Protection Act states:

A person violating any of Articles 24, 25 or 26, and failing to take corrective actions ordered by the competent authorities within the time limit set forth by the competent authorities, shall be punished by an administrative fine of not less than NT$20,000 and not more than NT$200,000.

[110] Article 15 of the Products Labelling Act states:

Where a commodity circulating on the market is found to be under any of the following circumstances, the competent authority under a special municipality or county (city) government, as the case may be, shall require, by giving a notice, the producer, manufacturer, or importer to rectify such defect within a given time limit; and if the producer, manufacturer, or importer fails to do so upon expiry of the given time limit, it may be imposed with a fine in an amount not less than New Taiwan Dollar Twenty Thousand (NTD 20,000) but not more than New Taiwan Dollar Two Hundred Thousand (NTD 200,000), and this fine may be assessed consecutively on a time-by-time basis until a satisfactory correction of such default:

1. Where the labelling of the commodity is made in a manner contrary to that as required in Paragraph One, Article 7 of this Law;
2. Where labelling and/or instruction booklet written in Chinese language are not provided as required in Paragraph One, Article 8 of this Law;
3. Where the labelling of the commodity is not made in accordance with the requirements set forth in Article 9 of this Law;
4. Where the labelling of commodity is not made in accordance with the requirements set forth in Article 10 of this Law; or
5. Where the specific particulars of labelling as required by a public notice given by the competent authority under Article 11 are not provided.

time limit, the goods shall be confiscated and destroyed.[111] The Act further provides that the manufacturer, seller, or importer of the goods that are to be confiscated shall immediately announce the termination of use or consumption of such goods and recall and destroy those said goods. Where necessary, the municipality or county/city competent authority may act for such recall and destruction with necessary charges.[112]

False, Exaggerated, or Misleading Advertisements Under the Act Governing Food Sanitation and the Fair Trade Act

The regulations on food advertisements and general advertisements could be relevant to cases concerning labelling fraud. Under Article 28 of the Food Act, the labelling, promotion, or advertisement of foods, food additives, food cleansers and food utensils, food containers, or packaging designated by the central competent authority in a public announcement shall not be false, exaggerate, or misleading. An administrative fine or penalty may be imposed on food businesses[113] or media businesses that violate this rule.[114]

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[111] Article 52 I(3) of the Act Governing Food Sanitation.

[112] Article 52 II of the Act Governing Food Sanitation.

[113] Article 45 of the Act Governing Food Sanitation states:

Those with violations of Paragraph 1 of Article 28 or the regulations prescribed by the central competent authority pursuant to Paragraph 3 of Article 28 shall be fined between NT$40,000 and NT$4,000,000; violation of Paragraph 2 of such article shall be fined between NT$600,000 and NT$5,000,000. Where the offense is repeated the enterprise may be ordered to terminate business, suspend business for a certain period of time, revoke all or part of the items listed in the company registration, business registration or factory registration, or registration of the food businesses. If registration of the food businesses is revoked, re-application for new registration within one (1) year shall be prohibited.

Food businesses in violation of the preceding food advertisement provisions shall be consecutively fined by such authority for each violation until the publication or broadcast is ceased.

Severe violation of any of the advertisement provisions under Article 28 shall not only be punished by the preceding two provisions, the competent authority shall order to halt all sale, supply or display; and shall publish or broadcast a specific number of corrective advertising in the same size and time period as the original within thirty (30) days of receiving the sanction order, which shall express regret and convey the message for elimination of error.

Violation of the preceding provisions by continuing to sell, supply, display or failure to publish or broadcast corrective advertising shall be fined between NT$120,000 to NT$600,000.

[114] Article 46 of the Act Governing Food Sanitation states:

Media businesses in violation of Article 29 shall be fined between NT$60,000 to NT$300,000, and may be consecutively fined. When the competent authority at the municipal level or county/city level impose fines in accordance with Paragraph 1 of the preceding article, the media businesses, and the relevant competent authority at the municipal or county/city level or industry competent authority shall be notified. The media businesses shall cease the broadcast or publication of the advertisement concerned from the day following its receipt of the above notification.

The Act also requires that foods shall not be labelled, promoted, or advertised as having medical efficacy. The central competent authority may prescribe restrictions on the sale, promotion, or advertising for special dietary foods or foods which are linked to chronic diseases or are unsuitable for long term consumption for children and persons with special needs. The regulations governing the food items; restrictions on sales, promotion, or advertising; prohibition of publishing and broadcasting; and other matters to be complied with shall be prescribed by the central competent authority.

Yet, a similar violation under the Fair Trade Act would attract a fine that is more than hundred times greater than the applicable fine under the Act Governing Food Sanitation. According to Article 21 of the Fair Trade Act:

> No enterprise shall make or use false or misleading representations or symbol as to price, quantity, quality, content, production process, production date, valid period, method of use, purpose of use, place of origin, manufacturer, place of manufacturing, processor, or place of processing on goods or in advertisements, or in any other way making known to the public.

The violator of Article 21 may be fined up to NT$25.[115] However, it appears only very serious would be fined under the Fair Trade Act. It seems GM product is less likely.

Media businesses continuing to publish or broadcast following the notification referred to in the preceding paragraph, in violation of Paragraphs 1 and 2 of Article 28 or any limit on advertisements or relevant regulations relating to the permanent suspension of advertisements prescribed by the central competent authority pursuant to Paragraph 3 of Article 28, shall be fined between NT$120,000 and NT$600,000 and shall be consecutively fined by such authority for each violation until the publication or broadcast is ceased.

When media businesses fail to cease publication or broadcasting following receipt of notification referred to in Paragraph 2, in addition to imposing fines in accordance with the preceding paragraph, the competent authority at the municipal level or county/city level shall also notify the competent authority of the media businesses at the municipal level or county/city level or its industry competent authority to address these issues.

[115] Article 41 of the Fair Trade Act states:

The Fair Trade Commission may order any enterprise that violates any of the provisions of this Law to cease therefrom, rectify its conduct or take necessary corrective action within the time prescribed in the order; in addition, it may assess upon such enterprise an administrative fine of not less than fifty thousand nor more than twenty-five million New Taiwan Dollars. Shall such enterprise fails to cease therefrom, rectify the conduct or take any necessary corrective action after the lapse of the prescribed period, the Fair Trade Commission may continue to order such enterprise to cease therefrom, rectify the conduct or take any necessary corrective action within the time prescribed in the order, and each time may successively assess thereupon an administrative fine of not less than one hundred thousand nor more than fifty million New Taiwan Dollars until its ceasing therefrom, rectifying its conduct or taking the necessary corrective action.

Fraud Under the Criminal Code

Theoretically, the labelling fraud of GM food can constitute criminal fraud under the Taiwan Criminal Code.[116] Yet, as extra criteria are imposed, a finding of criminal fraud is generally less likely in the cases of the labelling fraud concerning GM food. Usually, the aforementioned administrative sanction is necessary and is sufficient to deal with GM food fraud.

Liability

Genetic Technology and the R&D Phase: Public and Criminal Law

Once the aforementioned compliance regime is breached, the administrative penalty or criminal offence may come into play as an ex post measure for addressing violations. At this stage, a diverse range of penalties is available for the purposes of enforcement.

The strictest rules are those that apply to GM livestock. A breach of GM-livestock rules include the promotion and use of breeding flock or breeding stock that has not undergone any field tests or safety assessments. The transfer of genetic material without due permission is also prohibited. Offenders shall be subjected to a fine of more than NT$100,000, but less than NT$500,000.[117] Yet, if such situations led severe harm to human health, a criminal offense will apply: a prison term of not more than three years or a fine of not more than NT$300,000.[118]

[116] Article 339 of the Criminal Code states:

A person who by fraud causes another to deliver to him property belonging to such other or to a third person for purpose to exercise unlawful control over other's property for himself or for a fourth person shall be sentenced to imprisonment for not more than five years or short-term imprisonment; in lieu thereof, or in addition thereto, a fine of not more than one thousand yuan may be imposed.

A person who by the means specified in the preceding paragraph takes an illegal benefit for himself or for a third person shall be subject to the same punishment.

An attempt to commit an offense specified in one of the two preceding paragraphs is punishable.

[117] Article 38(1) of the Animal Industry Act.

[118] Article 38(3) of the Animal Industry Act.

Yet, for GM plants, only administrative penalties are imposed, although confiscation or destruction of the goods may be carried out.[119] Additionally, the offender may face the forced closure of any experimental initiatives.[120]

Finally, there is no mention of administrative penalty or criminal offence in the Fisheries Act for acts relating to GM aquaculture crops and livestock. There is only the requirement to cease any experiments, which is provided for in the Ordinance.[121]

Product Liability and the Food Phase: Public Law

In the area of GM food, the party that breaches registration and permission requirements, fails to provide required information on imports, presents false information on imports, or violates the Safety Evaluation rules could be found guilty of committing an administrative offence.[122]

For violations of labelling requirements, a notice shall be given for the goods to be recalled and for a correction made within a prescribed time period; the goods in question shall not be sold before the violation is corrected. In case the notice is not complied with within the prescribed time limit, the goods shall be confiscated and destroyed.[123] The manufacturer, seller, or importer of goods to be confiscated shall immediately announce the termination of use or consumption of such goods and recall and destroy the said goods. Where necessary, the municipality or county/city authority may act for such recall and destruction with necessary charges.[124]

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[119] Article 54 of the Plant Variety and Plant Seed Act states:

Any person in any of the following circumstances shall be fined up to five million New Taiwan Dollars but not less than one million New Taiwan Dollars:

1. importing or exporting in violation of the mandatory requirements governing approval under Paragraph 1 of Article 52,
2. promoting and sale without prior field testing in violation of Paragraph 2 of Article 52, or
3. conducting field testing in violation of the mandatory requirements governing administrative regulations of Paragraph 3 of Article 52.

Any plant illegally imported or exported, promoted, sold, or field-tested as set forth in the preceding Paragraph may be confiscated or destroyed. [emphasis added].

[120] Article 31, the Ordinance on the Management of GM Plants in Field Experiments.

[121] Articles 25 and 26 of the Ordinance of the Management of GM Aquaculture Crops and Livestock in Field Experiments.

[122] Article 47 of the Act Governing Food Sanitation states:

Anyone committing any of the following shall be fined between NT$30,000 and NT$3,000,000. In severe circumstances, the enterprise may be ordered to terminate business, suspend business for a certain period of time, revoke all or part of the items listed in the company registration, business registration or factory registration, or registration of the food businesses. If registration of the food businesses is revoked, re-application for new registration shall not be permitted within one year. [emphasis added].

[123] Article 52 I(3) of the Act Governing Food Sanitation.

[124] Article 52 II of the Act Governing Food Sanitation.

Summary

From the technology viewpoint, one can observed that the development of GM plants, animals, and aquaculture crops and livestock in Taiwan remains at a very early stage of RD&D. Any relatively mature technology in use for research is from abroad. As a result, the admitted and approved GM foods in Taiwan are mainly imported soybean and corn. Of course, part of the reason could be also related to US pressure for Taiwan to import soybean and corn.

The legal regime of GM technology and food is also reflective of the youth of the GM-research industry. The regulatory regime more focused on the pre-marketing, pre-food, and pre-product phase of RD&D on GM plants, animals, and aquaculture crops and livestock. A very comprehensive legal regime has been developed for the important RD&D issues of isolating experiment sites, the licencing of imports, and the regulation of field experiments and biosafety issues. At the food stage, the regulation concentrates on two types of food: corn and soybean. However, starting from January 2016, the legal regime will expand to all GM food.

On the point of rules on GM regulations, the main regulatory tool is administrative ordinances rather than statutes. One of the reasons could be the fact that at the RD&D phase the regulatory regime applies predominately to research institutes rather than to the private sector. This reality also reduces the need for 'law' to intervene. Similarly, at the food phase, the lenient rules on labelling and registration gives effect to a permissive regime that reduces the role of legislation.

However, given the potential for increasing numbers of domestic GM animals, plants, and aquaculture crops and livestock to pass the test during the R&D phase, the role of the law could become more important in the future. During the course of the past year, numerous food scandals have served to raise the awareness of the potential dangers of GM food. The legislative body has intensively passed several amendments to Food Act, which lead to the tightening of the current regulatory regime on GM food and products. However, it remains to be seen if the amended laws will be implemented effectively. It also remains to be observed whether anti-GM sentiment and legal developments will negatively impact Taiwan's domestic GM industries.

Chapter 13
Genetic Technology and Food Security: Country Report: The Macau S.A.R. (China)

Rostam J. Neuwirth

Macau is a small territory located on the Western Side of the Pearl River Delta near the South China Sea. In terms of its present status, it is a special administrative region of the People's Republic of China (PRC) established in line with the so-called "one country, two systems" principle laid down in the PRC Constitution. The scope of the Macau Special Administrative Region's (Macau SAR) political and regulatory powers is regulated in the Macau Basic Law (MBL), which grants the Macau SAR a wide range of political and economic rights. These rights also establish the Macau SAR as a local and global actor, with, on the one hand, a wide field of regulatory autonomy in domestic affairs, and also in international affairs, for instance, as a member of various international organizations, such as the World Trade Organization (WTO) on the other. The present report presents a brief overview of the legal regime governing the issue of genetic technology and food security in the Special Administrative Region of Macau.

General Information

This report is about the legal regime governing the issues of genetic technology and food security in the Special Administrative Region of Macau (Macau SAR) of the People's Republic of China (PRC). Macau derives its current legal status as a special administrative region of the PRC from Article 31 of the Constitution of the People's Republic of China (PRC), which incorporates the so-called "one country, two systems"

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principle.[1] In the case of Macau, the law that – in accordance with the Constitution of the PRC – lays out the special features of such special administrative regions, is the Basic Law of the Macau SAR (MBL), which was adopted by the Eighth National People's Congress of the PRC on March 31, 1993 and entered into force on December 20, 1999.[2] This date also marks the handover of the administration of Macau from Portugal to the PRC as laid down in the 1987 Sino-Portuguese Joint Declaration.[3] The MBL establishes Macau first as an inalienable part of the People's Republic of China but later gives rise to a high degree of autonomy in the governance of both its internal and external affairs in a wide range of policy fields. Externally, the autonomy covers particularly the right to "on its own, using the name "Macao, China", maintain and develop relations and conclude and implement agreements with foreign states and regions and relevant international organizations in the appropriate fields, including the economic, trade, financial and monetary, shipping, communications, tourism, cultural, science and technology, and sports fields".[4] As an example of such right, Macau is a founding member of the World Trade Organization (WTO) established in 1995 much like the Hong Kong SAR and Chinese Taipei. By contrast, the PRC, of which Macau is now an inalienable part, only became a WTO Member on December 11, 2001.

Use of GMO in Food Production

As for the issue of the use of genetically modified organisms (GMO) in food production, it is necessary to briefly point out some unique characteristics of Macau. First, Macau is a small territory of a size of little more than 30 square kilometers inhabited by an estimated population of 582.000 persons. However, due to its status as the world's largest gaming centre in terms of revenues,[5] Macau currently experiences visitor arrivals amounting to more than 28 million.[6] The close economic con-

[1] Art. 31 Constitution of the PRC, adopted in 1982 and amended the last time in 2004, which reads as follows: "The State may establish special administrative regions when necessary. The systems to be instituted in special administrative regions shall be prescribed by law enacted by the National People's Congress in the light of specific conditions"; Constitution of the People's Republic of China, adopted at the Fifth Session of the Fifth National People's Congress and promulgated for implementation by the Announcement of the National People's Congress on December 4, 1982, available on Westlaw China.

[2] Basic Law of the Macau Special Administrative Region of the People's Republic of China (MBL), adopted by the Eighth National People's Congress at its First Session on 31 March 1993, available at http://bo.io.gov.mo/bo/i/1999/leibasica/index_uk.asp

[3] Joint Declaration of the Government of the People's Republic of China and the Government of the Republic of Portugal on the Question of Macao (Beijing, 26 March 1987), available at http://bo.io.gov.mo/bo/i/88/23/dc/en/

[4] Compare Art. 1 and 136 MBL, supra note 2.

[5] See also Macau world's gaming capital, The Australian, (3 January 2013) at 16.

[6] Government of Macao Special Administrative Region, Statistics and Census Service, available at http://www.dsec.gov.mo/Home.aspx?lang=en-US

nection between the gaming industry in particular and tourism in general as well as due to its rich cultural history and convenient geographical location, Macau today not only features a large number but an equally rich repertoire of diverse cuisines. Local restaurants serve many Cantonese, Chinese, Portuguese, Japanese, African, Thai, Vietnamese, French and Italian delicacies. It is also host to both a large number of internationally acclaimed and award-winning restaurants,[7] as well as many excellent local food establishments, which Americans would term as "mom and pop businesses" and which may offer no more than a few tables or dishes but of great quality. The overall culinary situation in Macau has been described by the Macau Government's Tourist Office as follows:

> Among other things, Macau is famous for its cuisine and for the quality of the food served by the territory's restaurants and hotels. It is hard to find another city with such a concentration of restaurants offering so many different cuisines to suit so many tastes at all kinds of budget. In fact food has always played a major part in Macau society and is a good reflection of the community's long multicultural experience and present cosmopolitan way of life.[8]

It is fair to say that food plays a crucial role in Macau. This is also reflected in statistics, which list "food and non-alcoholic beverages" as the largest factor in household consumption, namely 27% followed closely only by household expenditure of 20%.[9] Food and beverages, among other items such as gold jewellery, mobile phones, watches, hand bags, vehicles, footwear and portable computers are also among the main products imported into the territory.

In sum, the growing role of the gaming industry and the dominance of the service industry have thus contributed to a decline of local production in various categories of goods. The most recent Trade Policy Review Report on Macau summarizes this development as follows:

> In 2011, services accounted for about 90% of GDP and employment; the gaming sector accounted for 45% of GDP and 20% of employment. Direct tax from gaming accounted for about 80% of total government revenue, which allowed the Government to maintain a fiscal surplus, and thus to continue to improve its infrastructure. Macao SAR has been transformed into the world's leading gaming destination.[10]

Finally, due to the size of the territory and its economic structure, there is hardly any agriculture nor is there much food production.[11] This also means that there are

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[7] See, e.g., Michelin Guide, Hong Kong – Macau 2013, 5th ed. (Clermont-Ferrand: Michelin Travel & Lifestyle, 2013) at 403–408, listing inter alia for Macau one three-starred, four two-starred and 2 one-starred restaurants, as well as eight "bib gourmand" restaurants which indicate inspectors' favourites for good value.

[8] Macau Government Tourist Office, "Dining in Macau", available at http://www.macautourism.gov.mo/en/discovering/dining.php

[9] Government of Macau Special Administrative Region Statistics and Census Service (DSEC), Macau Yearbook of Statistics 2011 (Macau: DSEC, 2012) at 102, available at: www.dsec.gov.mo

[10] WTO Trade Policy Review Body, Trade Policy Review: Macao, China (Report by the Secretariat), WT/TPR/S/281 (25 March 2013) at 6.

[11] Macau Yearbook of Statistics 2011, supra note 9.

no or only few facts and figures about the use of GMO available. As it is reflected in the recent adoption on a new law on food safety, there is, as shall be discussed below, a strong concern about food security and food safety in Macau, which is largely related to the dependence on food imports and the strong bilateral trade relations (and food imports) from the neighbouring PRC. As evidence of these strong concerns about food safety in Macau, one may mention the "melamine tainted milk powder" or "baby formula" scandal that hit the PRC in 2008, which made headlines across the world and which eventually led to the amendment of its regulatory regime and the adoption of a new Food Safety Law (FSL) in China in 2009.[12] However, the local concerns in Macau are usually about food quality and food safety in general and less about the specific role of GMO or other novel technologies applied to food processing.

Food Security

With regard to the concept of food security, it is first necessary to clarify the meaning of the concept in a global context, notably with relation to the related concept of "food safety". Food security is generally understood as to refer to the right to food or, inversely, the right to be free from hunger. This right is enshrined in Art. 25 (1) of the Universal Declaration of Human Rights (UDHR)[13] and the legally binding International Covenant on Economic, Social and Cultural Rights (ICESC).[14] Thus, in connection with the right to be free from hunger, "food security" can be defined as being primarily concerned with the "adequate supply and sufficient availability of food", i.e. quantitative aspects of food supply. By contrast, "food safety" can be understood as being predominantly concerned with the requirement that the food supplied does not harm those who consume it, i.e. qualitative aspects of food supply. In fact, it has been defined as follows:

> Food safety is generally recognized as the biological, chemical, or physical status of a food that will permit its consumption without incurring excessive risk of injury, morbidity, or mortality.[15]

The distinction between food security and food safety can also be arrived at indirectly by a systematic reading of various related international documents, such as,

[12] Food Safety Law of the People's Republic of China (FSL) (中华人民共和国食品安全法) promulgated by the Standing Committee of the National People's Congress on February 28, 2009; available on Westlaw China; see also Bian Yongmin, The Challenges for Food Safety in China, 53 China Perspectives 1 (2004).

[13] Universal Declaration of Human Rights, GA Res. 217(III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948) [Italics added].

[14] Art. 11 (1) of the International Covenant on Economic, Social and Cultural Rights (ICESC), adopted on December 16, 1966, 993 UNTS 3 (1966) (entry into force: January 3, 1976).

[15] Christine Boisrobert, et al. (eds), Ensuring Global Food Safety: Exploring Global Harmonization (London: Academic Press, 2010) at ix.

notably, the 1996 Declaration by the FAO on *World Food Security*[16] and the Millennium Development Goals (MDGs).[17]

The two concepts are, however, not only different but also closely related. This, in particular, when one approaches the issue from the perspective of sustainable development[18] and the principle of inter-generational equity.[19] These issues have been recognized in the human rights discourse by combining quantitative and qualitative considerations related to food security by the development from a "right to food" to a "right to adequate food".[20] This right was defined by the Committee on Economic, Social, and Cultural Rights as follows:

> The availability of food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances, and acceptable within a given culture;
>
> The accessibility of such food in ways that are sustainable and that do not interfere with the enjoyment of other human rights.[21]

This evolution marks an important point, particularly when considering the invention and application of new technologies in the production of food, such as those applied in genetically modified (GM) food, nanofoods,[22] or functional

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[16] World Food Summit, Nov. 13–17, 1996, Rome Declaration on World Food Security, U.N. Doc. A/52/132, E/1997/57 (May 5, 1997), available at http://www.fao.org/docrep/003/w3613e/w3613e00.htm

[17] General Assembly, United Nations Millennium Declaration, UN GA Res A/RES/55/2 (September 18, 2000) [hereinafter MDGs]; available at http://www.un.org/millennium/declaration/ares552e.pdf

[18] Report of the World Commission on Environment and Development (WECD), Our Common Future, transmitted to the General Assembly as an Annex to document A/42/427 – Development and International Co-operation: Environment, available at http://www.un-documents.net/wced-ocf.htm, defining sustainable development as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs".

[19] See, e.g,. Edith Brown Weiss, In Fairness to Future Generations: International Law, Common Patrimony and Intergenerational Equity (Tokyo: The United Nations University, 1989) at 95 ("Principles of equity between generations lead to a set of planetary, or intergenerational, rights and obligations, with associated international duties of use. Planetary rights [and obligations] are the rights [and obligations] which each generation has to receive [and to pass on] the planet in no worse condition than that of the previous generation, to inherit comparable diversity in the natural and cultural resource bases, and to have equitable access to the use and benefits of the legacy").

[20] See, e.g., Stefania Negri, Food Safety and Global Health: An International Law Perspective, 3 Global Health Governance 1 (2009), available at http://www.ghgj.org, George Kent, Freedom from Want: The Human Right to Adequate Food (Washington, DC: Georgetown University Press, 2005), Kerstin Mechlem, "Food Security and the Right to Food in the Discourse of the United Nations", (2004) 10 European Law Journal 631; and Jean Ziegler, Christophe Golay, Claire Mahon & Sally-Anne Way, The Fight for the Right to Food: Lessons Learned (Geneva: Graduate Institute, 2011).

[21] Committee on Economic, Social and Cultural Rights, General Comment No. 12, E/C.12/1999/5 (May 12, 1999), at para. 8.

[22] On regulatory issues related to nanotechnology, see generally Iris Eisenberger, et al., Nano Regulation in the European Union, (2010) 17 Nanotrust Dossier 1; available at http://epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier017en.pdf

foods.[23] It is in these novel foods that the contacts between the two concepts intensify because these novel foods are often invoked as a means to secure the food supply for a steadily growing world population on the one hand but at the same they are also considered to possible bear unintended long-term consequences or various risks.[24] Food safety and food security are thus closely intertwined because required standards of food quality may be sacrificed for adequate levels of supply of food. Or else, only if food supply is secured, concerns about food safety can be duly addressed as it may become necessary that in the attempt to secure the food supply one may be forced to compromise on food safety, i.e. the quality of the food supplied.

Having clarified the meaning of the concepts of food safety and food security, we can now turn to the legal definition of food safety in Macau. In this regard, Macau has recently passed a new Food Safety Law, which was published on April 22, 2013 and will enter into force on October 20, 2013.[25] In the two official languages of Macau, Chinese and Portuguese, the new law is called "食品安全法"(*shi pin an quan fa*) and "*Lei de segurança alimentar*" was published on April 22, 2013.

In view of the wide scope of the meaning of the Portuguese term "*segurança",* a systemic reading of this first article recalls the distinction made between "food safety" and "food security" and underscores that the present law is essentially about "food safety". A similar conclusion derives from the text of the law in its authentic Chinese version (食品安全法) (*shi pin an quan fa*). This opinion is further reinvigorated by the objective and scope of the law as laid down in Articles 1 and 2 MFSL. Article 1 MFSL reads as follows:

> This law regulates the supervision and administration, the preventive measures, the control and treatment of the risks and the mechanisms for the handling of incidents in the field of food safety, in order to guarantee the health and safety of the lives of people.[26]

In terms of scope, the MFSL stipulates that it applies to "the production and commercialization of foodstuff, as well as the use of food additives and products related to the processing of foodstuff" but excludes medicines as well as traditional

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[23] See also Manashi Bagchi et al., Bio-Nanotechnology: A Revolution in Food, Biomedical and Health Sciences (Hui: Food Science and Technology, 2013).

[24] See, e.g., Jorge Niosi & Susan E. Reid, "Biotechnology and Nanotechnology: Science-based Enabling Technologies as Windows of Opportunity for LDCs?", (2007) 35 World Development 426; Gary E. Marchant & Douglas J. Sylvester, "Transnational Models for Regulation of Nanotechnology", (2006) 34 The Journal of Law, Medicine & Ethics 714; and Organization for Economic Cooperation and Development (OECD), Small Sizes that Matter: Opportunities and Risks of Nanotechnologies (Paris: OECD, 2005).

[25] See the Macau Food Safety Law (MFSL) [食品安全法(第5/2013 號法律) or Lei de segurança alimentar (Law No. 5/2013)], Official Bulletin No. 17/2013, Series I, pp. 259–69 (April 22, 2013), available at http://www.al.gov.mo/lei/leis/2013/2013-05/po.htm available at http://www.al.gov.mo/lei/leis/2013/2013-05/po.htm; see also the corrections to the law ("Declaração de rectificação") concerning Articles 8 and 28 MFSL, Official Bulletin No. 24, Series I, p. 514 (June 10, 2013), available at http://bo.io.gov.mo/bo/i/2013/24/rectif01.asp

[26] Art. 1 MFSL, supra note 25 [translation by author].

Chinese medicines or their ingredients.[27] Further clarifying the scope, Article 3 (1) MFSL clarifies the meaning of "food" by stipulating as follows:

> "food" means any substance, treated or not, intended for human consumption, including drinks and products such as chewing gums, as well as all the ingredients used in the production, preparation and handling of food.[28]

In the following, the definition of "food safety" in the MFSL is similar to the one applied by the Codex Alimentarius[29] and reads as follows:

> "Food safety", in which foods are not toxic or harmful, whose nutritional values are in accordance with the requirements, and which does not derive any harm acute, sub-acute, or chronic human health[30];

The definition of food safety in Macau, therefore, does not explicitly refer to genetic technology and must be deemed to reflect a more general concern with food safety also in context with pandemic diseases such as avian influenza, as for instance, expressed by the Chief Executive of the Macau SAR in his policy addresses of 2006 and 2009.[31] Similar concerns have ultimately also led to the formulation and adoption of a new law on food safety.[32]

Legal Superstructure

As far as the overall legal framework of the Macau SAR governing the issues of food security and food safety are concerned, it is necessary to point out again the special legal status of the Macau SAR as an integral part of the PRC. The scope and powers linked to this status are outlined in the Macau Basic Law (MBL), which also grant Macau a vast area of competences at the international level.[33] Accordingly, at the international level, Macau has thus signed numerous international treaties.[34] Among them feature also the International Covenant on Economic, Social and

[27] Art. 2 MFSL, supra note 25.

[28] Compare Art. 3 (1) MFSL, supra note 25.

[29] Codex Alimentarius Commission, Procedural Manual (20th ed. 2011), available at http://www.codexalimentarius.org/roster/detail/en/c/80349/

[30] Compare Art. 3 (5) MFSL, supra note 25.

[31] Policy Addresses for the Fiscal Year 2006 and 2009 of the Macao Special Administrative Region (MSAR) of the People's Republic of China (2006) at 15 and at 4, available at http://portal.gov.mo/web/guest/govinfo/policy-address

[32] See the "Nota Justificativa" (Background Note) for the proposal of the Food Safety Law in the Legislative Assembly of the MSAR at 1, available at http://www.al.gov.mo/lei/leis/2013/2013-05/po.htm

[33] Compare Art. 1 and 136 MBL, supra note 2.

[34] For a list of convention to which the Macau SAR is a signatory, see also the MSAR Law Reform and International Law Bureau, List of Conventions, available at http://www.dsrjdi.ccrj.gov.mo/en/tratadospt.asp

Cultural Rights (ICESC), which also recognizes the right to food security.[35] Equally important for the issue of public health and food safety, Macau has also been a member of the World Health Organization's Western Pacific Regional Committee since 1993, i.e. a subdivision of the organization which jointly with the Food and Agricultural Organization (FAO) issues various international food standards, guidelines, and codes of practice known as the Codex Alimentarius.[36]

Moreover, as far as international trade in foodstuff is concerned, the Macau SAR, under the name of "Macao, China", is a founding member of the WTO established in 1995 much like the Hong Kong Special Administrative Region and Chinese Taipei. Under the single package deal concluded by the Uruguay Round negotiations, this means that all WTO administered agreements are also applicable to Macau. For particular relevance to the issue of food safety, this also includes the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Agreement on Technical Barriers to Trade (TBT Agreement) as well as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[37] Also important for the treatment of imported goods or services is that based on Article 111 MBL Macau is obliged to pursue "the policy of free trade and safeguard the free movement of goods, intangible assets and capital". This means that Macau maintains the status of a free port where (most) goods enter with zero tariffs and face few border measures.[38]

At the regional level, and due to its status as a separate customs territory, Macau has also concluded a regional trade agreement (RTA) with the PRC, the so-called "Mainland and Macao Closer Economic Partnership Arrangement" (CEPA), which was signed and notified to the WTO under Art. XXIV of the General Agreement on Tariffs and Trade (GATT) and Art. V of the General Agreement on Trade in Services (GATS) on December 27, 2003.[39] In the CEPA, Art. 17 also lays out as one of the areas of cooperation the issue of "food safety" next to related areas, such as "commodities inspection, inspection and quarantine of animals and plants, sanitary quarantine, certification, accreditation and standardization management".[40] Much earlier, namely in 1992, the Macau SAR also concluded a Trade and Cooperation Agreement with the predecessor of the European Union, the European Economic Community,

[35] Art. 11 (1) ICESC, supra note 14.

[36] World Health Organization Western Pacific Regional Committee, Countries and Areas; available at http://www.wpro.who.int/countries/en/

[37] Agreement on the Application of Sanitary and Phytosanitary Measures, the Agreement on Technical Barriers to Trade, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), reprinted in 33 ILM 1144.

[38] See Article 110 MBL, supra note 2; see also Trade Policy Review Body, Trade Policy Review: Macau, China (Report by the Secretariat), WT/TPR/S/281 (March 25, 2013) at 7.

[39] WTO Homepage, List of all RTAs", available at http://rtais.wto.org/UI/PublicShowRTAIDCard.aspx?rtaid=56; the Mainland and Macao Closer Economic Partnership Arrangement (CEPA), available at http://www.cepa.gov.mo/cepaweb/front/eng/itemI_2.htm

[40] Id.

which also lists various areas for cooperation related to foodstuff.[41] Under this agreement, the two parties meet regularly and the EU also issues annual reports.[42]

In sum, the legal status of the Macau SAR provides for an interesting combination of norms originating from the local, national, regional, and global level coming together, which elsewhere has been termed as "governing glocalization".[43] This "glocal" or both global and local condition is also reflected in the process of governing the issue of food safety. Providing the link between the external and internal powers, the MBL, which can be described as a constitutional document for Macau, also contains some general provisions relevant for the issues of food security and food safety. This is, first of all, exemplified by some of the articles of the MBL which codify some of the fundamental rights granted to permanent and non-permanent residents of Macau but also extended to persons other than Macau residents.[44] In this regard, the MBL explicitly mentions several fundamental rights, which may also be relevant to food safety: It first recognizes human dignity as being inviolable and equally guarantees the freedom of religious belief, which may also have significant implications for food safety.[45] In addition, Macao residents shall have the right to social welfare in accordance with law, which may also be interpreted so as to include the adequate supply of safe food.[46] Last but not least, Article 40 of the MBL stipulates that the provisions of several international agreements, to which Macau is a signatory, shall remain in force, which also includes the ICESC mentioned before.[47]

Outline of the Relevant Law

The law or laws and regulations in the Macau SAR relevant to the interface between food safety or genetic technology and food law have recently been amended by the adoption and entry into force of a new Macau Food Safety Law (MFSL). The new MFSL counts a total of 31 articles structured in a total of 4 chapters. The MFSL was adopted with the particular aim of restructuring the regulatory regime governing

[41] The Agreement for Trade and Cooperation Between the European Economic Community and Macao, OJ L404/27 (December 31, 1992).

[42] See, e.g., European Commission, Joint Report to the European Parliament and the Council, Macao Special Administrative Region: Annual Report 2011, JOIN(2012) 10 final (May 3, 2012).

[43] Rostam J. Neuwirth, "Governing 'Glocalisation': A View from the Macau Special Administrative Region of China", (2011) 3 City University of Hong Kong Law Review 89.

[44] Compare Art. 24 in connection with Art. 43 MBL, supra note 2.

[45] Art. 34 MBL, supra note 2; see also Committee on Economic, Social and Cultural Rights, General Comment No. 12, para. 4, E/C.12/1999/5 (May 12, 1999), affirming that "the right to adequate food is indivisibly linked to the inherent dignity of the human person and is indispensable for the fulfillment of other human rights enshrined in the International Bill of Human Rights"; available at http://daccess-ods.un.org/TMP/2741040.58742523.html

[46] Art. 39 MBL, supra note 2.

[47] Art. 40 MBL, supra note 2.

food safety, notably in view of the possibilities of dispersion, overlap, lacunae, or conflicts between legal norms and institutional competences in this matter and to improve their monitoring and implementation.[48] In this regard, the previous regulatory framework governing food safety was both divided and shared between several Departments, such as the Civic and Municipal Affairs Bureau (IACM), the Macao Economic Services (MES), the Macau Government Tourism Office (MGTO), the Macau Customs Service, the Consumer Council, the Macau Public Works and Transport Bureau (DSSOPT), and the Macau Health Services (SSM) as well as several related laws, decree laws and administrative regulations.[49] To remedy the problems derived from such fragmentation and to reform the existing regulatory framework, the Macau Government recognized the close link between food safety and people's well-being and pledged to undertake the following:

> To introduce more effective monitoring, respond to and resolve various food safety problems, the Government will establish a centre for food safety under the Civil and Municipal Affairs Bureau. The centre will be responsible for overall food supervision and related coordination work.[50]

The mentioned centre in charge of supervising and monitoring the implementation of the MFSL is the Civic and Municipal Affairs Bureau (IACM). As a result, the new law on food safety promises to step up the level of coordination and coherence by concentrating the main supervisory competence for food safety in the hands of the IACM and to create a Food Safety Center within its ambit.[51] In substantive terms, however, the legal regime governing the issue of food safety is still fragmented, notably between the following laws and regulations[52]:

> Administrative Regulation No. 13/2013 on the maximum limits of veterinary medical residues in foodstuff[53];
>
> Macau Food Safety Law (MFSL) – Law No. 5/2013[54];

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[48] See the "Nota Justificativa" (Background Note), supra note 32, at 1, available at http://www.al.gov.mo/lei/leis/2013/2013-05/po.htm

[49] See Tong Ka Io & Sio Hao Leng, "Experiências de emergência e recomendações sobre segurança alimentar em Macau", (2010) 22 Administracão 455 at 458–9, available at http://www.safp.gov.mo/safppt/download/WCM_004620

[50] See the Policy Address for the Fiscal Year 2010 of the Macao Special Administrative Region (MSAR) of the People's Republic of China (2010) at 10, available at http://portal.gov.mo/web/guest/govinfo/policy-address

[51] Id.

[52] For an overview of the laws and regulations amending the cited laws, see the "Legal Regime Concerning Offenses against Public Health and the Economy"; available at http://pt.io.gov.mo/Legis/record/121810.aspx

[53] Administrative Regulation No. 13/2013 on the Maximum Limits of veterinary medical residues in foodstuff ("Limites máximos de resíduos de medicamentos veterinários nos alimentos"), published in the Official Bulletin No. 24/2013, Series I, pp. 510–11 (June 10, 2013), available at http://bo.io.gov.mo/bo/i/2013/24/regadm13.asp

[54] See MFSL, supra note 25.

Dispatch of the Chief Executive No. 556/2009 on Food additives[55];
Law No. 6/96/M establishing the legal regime concerning offenses against public health and the economy amended by Law No. 3/2008 on the prohibition of "pyramid sales scheme"; and by Law No. 7/2005[56];
Administrative Regulation No. 40/2004[57]; and
Decree Law No. 50/92/M concerning the labeling of foodstuff (amended by Administrative Regulation No. 7/2004; Decree Law No. 56/94/M).[58]

In addition to the domestic laws and regulations, as was presented already, there exist several international instruments which also play an important role. This includes notably the ICESC, the so-called "Mainland and Macao Closer Economic Partnership Arrangement" (CEPA) and the Trade and Cooperation Agreement with the predecessor of the European Union, the European Economic Community. As for other international standards, the new law was based or took standards formulated by the Food and Agricultural Organization (FAO) and the World Health Organization (WHO) as well as regulatory regimes of the PRC, Hong Kong, Taiwan, and Singapore as references but does not explicitly acknowledge them.[59] This is also reflected in a recent notification of the new law to the WTO, which does not mention any international standards but describes the content of the law as follows:

> The subject of Law No. 5/2013 "Lei de segurança alimentar" (Food Safety Law) is to protect public health and safety through regulating the supervision and management of food safety, food safety risk prevention, control and countermeasure, as well as food safety incident management. The law is applicable to food production and business operation, as well as the use of food additives and food related products in commercial foodstuffs, but not for medicine that contains proprietary Chinese medicines and other Chinese herbal medicines specifically for sale in Chinese pharmacies, that are regulated by other legislations. "Lei de segurança alimentar" lists the authority of IACM in the food safety area, and the obligation of public or private entities to provide assistance. The law elaborates the establishment of food safety standards, risk monitoring, risk assessment and prevention and control measures under the premise of prevention and control. In addition, the law also includes a penalty system, including criminal liability and administrative penalties.[60]

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[55] Dispatch of the Chief Executive (Despacho do Chefe do Executivo) No. 556/2009, Official Bulletin No. 2/2010, Series I, pp. 6–33 (January 11, 2010), available at http://bo.io.gov.mo/bo/i/2010/02/despce.asp#556

[56] Law No. 6/96/M (July 15, 1996) on the legal regime governing violations against public health and the economy [Lei n.° 6/96/M – Aprova o regime jurídico das infracções contra a saúde pública e contra a economia], (1996) 29 Official Bulletin 1227 (15 July 1996), which amended the Decree Law (Decreto-Lei) No. 50/92/M) (August 17, 1992) on the labelling of food; available at http://bo.io.gov.mo/bo/i/96/29/lei06.asp

[57] Administrative Regulation (Regulamento Administrativo) No. 40/2004 on sanitary and phytosanitary control, Official Bulletin No. 51/20004, Series I, pp. 2194–2201 (December 22, 2004), available at http://bo.io.gov.mo/bo/i/2004/51/regadm40.asp

[58] Decree Law (Decreto-Lei) No. 50/92/M, Official Bulletin No. 33/1992, Series I, p. 3404 (August 17, 1992), available at http://bo.io.gov.mo/bo/i/92/33/declei50.asp

[59] See the "Nota Justificativa" (Background Note), supra note 32, at 1.

[60] See Committee on Sanitary and Phytosanitary Measures, Notification by Macao, China, G/SPS/N/MAC/11 (3 June 2013).

As can be seen from this brief description, there exist further laws and regulations which directly and indirectly address the issues of food safety in general and of genetic technology in particular.

Admission

Restriction of GMO

As far as the possible restrictions of Genetically Modified Organisms (GMOs) are concerned, the MFSL stipulates that it applies to both the production and commercialization of foodstuff (Art. 2 (1) MFSL). However, as there is hardly any food production in Macau, notably based on agriculture, the central focus of the law is on the commercialization or import of foodstuff into the Macau SAR. In this regard, the MFSL does not contain any specific references to GMOs or other novel foods, such as foods produced using nanotechnology. Instead, the law merely mentions "food additives" and defines them as follows:

> "Food additive" means any substance, with or without nutritional value, which by itself is not usually considered as food or its characteristic ingredient, intentional addition of which, with technological or organoleptic purpose, at any stage of production and marketing of a foodstuff, has the consequence of their incorporation in the presence of a derivative thereof in foodstuff or modifications of its characteristics, other than substances added in order to improve the nutritional properties of foods.[61]

With regard to food additives, a Dispatch by the Chief Executive from 2009, lists the various substances that qualify as food additives.[62] An older law adopted in 1996 that equally addresses the issue of food safety is called the Law on legal regime governing the offenses against public health and the economy.[63] This law too does not explicitly mention GMOs but instead speaks of "abnormal substances", for the production, sale, or import of which it foresees the imposition of sanctions.[64] Finally, the absence of an explicit statement on GMOs is also found in the Penal Code of Macau, where Article 269 lists the crime of the "corruption of food or medicinal products", which foresees a term of imprisonment from 1 to 8 years and up to 5 years for negligence.[65]

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[61] Art. 3 (2) MFSL, supra note 25.

[62] See Dispatch of the Chief Executive (Despacho do Chefe do Executivo) No. 556/2009, Official Bulletin No. 2/2010, Series I, pp. 6–33 (January 11, 2010), available at http://bo.io.gov.mo/bo/i/2010/02/despce.asp#556

[63] Law No. 6/96/M, supra note 56.

[64] See Art. 20 (1) Law No. 6/96/M, supra note 56.

[65] Art. 269 Macau Penal Code, approved by Decree Law No. 58/95/M on November 14, 1995 and amended by Laws No. 6/2001, 3/2006, 6/2008, 11/2009 and 17/2009; available at http://bo.io.gov.mo/bo/i/95/46/codpenpt/indice_art.asp

Admission of GMO in Food Production

As there is no explicit mention of GMO in the legal regime governing food safety in the Macau SAR, it must be generally concluded that GMOs are admitted, both in terms of local production and the import of foreign products containing GMOs. However, in both cases, the use of GMOs must comply with all the required laws and regulations governing food safety in particular and public health in general. It thus means that if a product, either produced in Macau or imported to Macau, which contains GMO has caused a food safety concern, it will be subject to the sanctions provided by the respective laws and regulations.

Threshold Values

As there is no explicit mention of GMOs in the entire regulatory framework of the Macau SAR, there are also no explicit threshold values. As briefly mentioned before, the Chief Executive has adopted an administrative regulation on the maximum limits of veterinary medical residues in foodstuff.[66] A similar regulation addressing potential risks related to GM foodstuff could be adopted in the future.

Implementation and Enforcement, Controlling Regime

Prior to the enactment of the new Food Safety Law, the institutional responsibility of enforcing and monitoring food safety in the Macau SAR was both divided and shared between several governmental departments, namely, the Civic and Municipal Affairs Bureau (IACM), the Macao Economic Services (MES), the Macau Government Tourism Office (MGTO), the Macau Customs Service, the Consumer Council, the Macau Public Works and Transport Bureau (DSSOPT), and the Macau Health Services (SSM).[67] In 2010, the Macau Government recognized the close link between food safety and people's well-being and pledged to remedy the problems derived from such fragmentation and to reform the existing regulatory framework by undertaking the following:

> To introduce more effective monitoring, respond to and resolve various food safety problems, the Government will establish a centre for food safety under the Civil and Municipal Affairs Bureau. The centre will be responsible for overall food supervision and related coordination work.[68]

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[66] See Administrative Regulation No. 13/2013 on the Maximum Limits of veterinary medical residues in foodstuff ("Limites máximos de resíduos de medicamentos veterinários nos alimentos"), supra note 53.

[67] See Tong Ka Io & Sio Hao Leng, supra note 49, at 458–9.

[68] See the Policy Address for the Fiscal Year 2010 of the Macao Special Administrative Region (Macau SAR) of the People's Republic of China (2010) at 10, available at http://portal.gov.mo/web/guest/govinfo/policy-address

To realize this objective, the proposal for a new law on food safety planned to focus the supervisory competence for food safety in the hands of the IACM and to create a Food Safety Center within its ambit.[69] In the past, the IACM had been given a wide range of responsibilities including inter alia the management of recreational sites, the provision of civic education, the maintenance of public parks and the city's sanitation, as well as cemeteries and burial sites and, last but not least, now also the management and supervision of food safety issues.[70] From an international perspective, it is also noteworthy that the IACM was named the SPS enquiry point for the WTO and as such responsible for the implementation of SPS regulations and measures.[71]

Based on Article 4 MFSL, the new law does indeed allocate several important competences related to food safety to the IACM. These competences include a broad range from the supervision and management of food safety, on-site inspections, and the collection of samples to the treatment of food safety incidents and various related duties to the dissemination of information. With the MFSL, the IACM was established as the prime supervisory unit in charge of the coordination of food safety-related activities, and obliges other public and private entities, such as the health service, tourism, and other departments to cooperate. Additionally, the MFSL still stipulates a general duty for all public authorities to exchange information relevant to food safety.[72]

Labelling Regime

Labelling

As far as the specific issue of labelling of foodstuff and food products in the Macau SAR are concerned, the most relevant law is the Decree Law No. 50/92/M or "Macau Labeling Decree Law" (MLDL), which was first adopted on August 17, 1992 and amended twice since then.[73] As far as the considerations leading to the adoption of

[69] See the "Nota Justificativa" (Background Note), supra note 48, at 1.

[70] See also the IACM Webpage, available at http://www.iacm.gov.mo/e/default/

[71] Note that the Administrative Regulation (Regulamento Administrativo) No. 40/2004 on sanitary and phytosanitary control, Official Bulletin No. 51/20004, Series I, pp. 2194–2201 (December 22, 2004), available at http://bo.io.gov.mo/bo/i/2004/51/regadm40.asp) regulates SPS-related matters in Macao SAR and that the Civic and Municipal Affairs Bureau of Macao (IACM) is responsible for formulating and implementing SPS regulations and measures, which is also the SPS enquiry point for the WTO; see WTO, Trade Policy Review: Report by the Secretariat: Macao, China, WT/TPR/S/281 (March 25, 2013) at 3.45.

[72] Art. 6 MFSL, supra note 2.

[73] Decree Law (Decreto-Lei) No. 50/92/M (establishing the conditions to be complied with for the labeling of foodstuffs ready to be supplied to the final consumer), Official Bulletin No. 33/1992, Series I, p. 3404 (August 17, 1992) (amended by the Decree Law No. 56/94/M in 1994 and by the Administrative Regulation No. 7/2004 in 2004), available at http://bo.io.gov.mo/bo/i/92/33/declei50.asp

the MLDL are concerned, the perambulatory part of the Law first recognizes that labelling, through the information provided on the packaging of products, including among other data on the nature, composition, quantity or expiration date of the product, in particular, constitutes an important means for the adequate information of consumers thus enabling them to make a conscious and rational choice.

More concretely, Article 1 MLDL lays out the scope of the decree law by stipulating that it applies to foodstuff from the moment it is made accessible to the final consumer in its "pre-packaged or not pre-packaged form" and regardless of whether it is of domestic origin or has been imported. Consequently, Article 2 (1) MLDL provides the definitions of the meaning of the most important concepts, such as "labelling, foodstuff, packaging, pre-packaged foodstuff, ingredients, food additives, expiry date, net quantity, lot (or set of units), and fresh or perishable foodstuff". In paragraph 2, Article 2 clarifies that the term "food additive" does not include "substances added to food in order to enhance their nutritional properties". In Article 3 (1) MLDL, the decree law provides a list of the data that have to be included in the label and which include the designation of sale, list of ingredients, the minimum durability (or expiry date), and the name of the business or company plus the address of the importer or person responsible for the labeling. As outlined in Articles 14–16 MLDL, paragraph 2 of Article 3 MLDL requires additional information regarding the country of origin, special conditions for storage and use so as to avoid confusion of the consumer. Paragraph 3 of Article 3 MLDL adds additional requirements for the labeling of not-prepackaged foodstuff, namely, the designation of sale, the country of origin, a reference identifying the lots (or set of units) and the expiry date.

The mentioned requirements do not apply, however, to foodstuffs sold by food stalls, whose activity consists of making foodstuff that is prepared for immediate consumption (Article 3 (4) MLDL). Articles 4, 5, 7 and 11 MLDL further clarify the meaning and requirements attached to the concepts of "designation of sale", "list of ingredients", "expiry date", and "net quantity". Various categories of foodstuff, such as products containing only one ingredient, fruits and vegetables, carbonated water, vinegar or some dairy products are exempted from the requirement of providing these specifications (Article 6 and 9 MLDL). As far as the lot (or set of units) is concerned, the decree law states that it shall be determined by the producer, manufacturer, or packager, but this requirement can be waived in certain circumstances Articles 12 and 13 MLDL).

Interesting for the multilingual background of the Macau SAR, Article 8 MLDL sets out the linguistic requirements for the information provided on the label. In this regard, it stipulates that the information listed in Article 4 MLDL must be provided in one of the following three languages, namely, Chinese, Portuguese or English. Only pre-packaged foodstuff produced in the territory of the Macau SAR must always be provided in both Chinese and Portuguese, i.e. its official languages.

As far as the responsibility and liability of the labeling is concerned, Article 10 MLDL identifies the entity which has introduced the relevant pre-packed foodstuff to the domestic market, such as the importer, producer, or retailer.

Finally, as far as the enforcement of the present law is concerned, Article 18 MLDL designates the *Direcção dos Serviços de Economia* (Directorate of Economic

Services) as the main organ but other entities, which might become aware of related problems, have a duty to inform the said Directorate. It is not entirely clear to what extent the new Food Safety Law, which tries to concentrate food safety related concerns in the hands of the IACM will affect this provision in practice. Supporting the enforcement of the labeling requirements are various sanctions foreseen in the case of a contravention of the law, which are laid down in Article 19 MLDL and which range from pecuniary fines from a minimum of 1.000 Patacas (MOP) [1.000 MOP = approx. 90 Euros] to a maximum of 50.000 MOP. The responsibility for the imposition of sanctions and their proceedings are further regulated in Articles 20–23 MLDL but to not affect a possible criminal liability (Article 24 MLDL).

In general, there are two more legal instruments, which further govern and complement the regulation of labelling in the Macau SAR. As it is also indicated in the preamble of the MLDL, the labeling of foodstuff constitutes an important means for the adequate information of consumers and hence serves the goal of the protection of consumers. The more general legal instrument addressing the concerns and interests of consumers is the Macau Consumer Protection Law (MCPL), which was adopted in 1988 and also altered several times since then.[74] To the difference of the MLDL, the MCPL thus protects the issue of food safety from a slightly different angle, namely one which focuses on the protection of consumers in general. To this end, the perambulatory part of the MCPL recognises that "misleading advertising and unfair and anti-competitive practices as well as offenses against the economic order and public health regime, should be subject to appropriate specific legislative measures". Following a definition of the consumer in Article 2 MCPL, Article 3 MCPL lists the criteria for the rights of a consumer as follows:

> The consumer has the right:
>
> a. to the protection of health and safety against unfair or irregular publication or supply of goods or services;
> b. to education and information;
> c. to protection against the risk of a violation of their interests;
> d. to the prevention and compensation of damages, both individual or collective;
> e. to an affordable justice; and
> f. to the participation in the legal or administrative definition of their rights and interests.[75]

With particular relevance for the issue of the safety of foodstuff, Article 4 MCPL contains a general prohibition of the supply of certain goods or services. These goods and services also potentially include foodstuff as the relevant provision prohibits the "supply of goods or services that, when used under normal or foreseeable conditions,

[74] The Consumer Protection Law Law No. 12/88/M of June 13, 1988 ("Defesa do consumidor"); available at http://bo.io.gov.mo/bo/i/88/24/lei12.asp. See also Article 1 (2) Administrative Regulation (Regulamento Administrativo) No. 17/2008 on the General Product Safety Regime; available at http://bo.io.gov.mo/bo/i/2008/27/regadm17.asp, which was decreed by the Chief Executive to further concretize the general product safety regime but which explicitly exempts food from its regulatory scope.

[75] For a further clarification of the meaning and scope of these rights, see Articles 7–11 MCPL.

involve a danger to the health or safety of consumers" (Article 4 (1) MCPL. Taking into account the implications that progress and changes in technology and science may have on law, Article 5 MCPL aims at preventing generic risks by periodically publishing lists of identifiable substances that may be considered toxic or dangerous, as well as additives, colorings and preservatives allowed in food products. In order to address various special risks, the MCPL contains a selected list of products, for which it foresees the adoption and application of special regulatory measures, which, among others, explicitly mention "(a) prepackaged food products; (b) frozen food; and (c) objects and materials intended to be put in contact with food (Article 6 MCPL).

From an institutional perspective, it is worth mentioning that Article 12 of the said law had also established a Consumer Protection Council (*Conselho de Consumidores*), but this provision was subject to a later amendment.[76] According to the amended version, the Consumer Protection Council has numerous duties, including (but not limited to), formulation of consumer protection policies, the cooperation with related entities, the handling of consumer complaints and the provision of mechanisms for their conciliation, meditation or arbitrations.[77]

Finally, it is necessary to briefly mention the Macau Foreign Trade Law (MFTL) adopted in 2003, which – in line with Macau's status as a free port and commitment to a free trade policy – governs the import, export and transition of all kinds of merchandise or goods.[78] The MFTL also authorizes the Chief Executive to exceptionally, for reasons of public interest, prohibit, restrict or condition, by order the import, export and transit of certain goods. These reasons include notably "imperatives of public safety", "prevention of fraudulent practices", the protection of life, health or safety of persons, and the protection of the environment.[79] For this purpose, the MFTL also contains several provisions regarding the imposition of fines and other sanctions.

Legislation Addressing Labelling Fraud

As outlined above the central legal instrument addressing all labeling issues is the Macau Labeling Decree Law (MLDL) as well as various related laws and administrative regulations. The most pertinent provision concerning labelling fraud in the MLDL is found in Article 19 MLDL, which lists the sanctions for various violations

[76] See Law No. 4/95/M – Restructuring the Consumer Protection Council (Lei n.° 4/95/M – Reestrutura o Conselho de Consumidores), which revoked Articles 12 and 25 of the Law No. 12/88/M; available at: http://bo.io.gov.mo/bo/i/95/24/lei04.asp. Please note that some provisions of Law No. 4/95/M have been amended again by Law No. 1/98/M (Lei n.° 1/98/M – Altera a Lei n.° 4/95/M, de 12 de Junho. (Reestrutura o Conselho de Consumidores), available at: http://bo.io.gov.mo/bo/i/98/22/lei01.asp)

[77] Article 2 of the Law No. 4/95/M, ibid.

[78] Law No. 7/2003 – Macau Foreign Trade Law (MFTL) (Lei n.° 7/2003 – Lei do Comércio Externo), (2003) 25 Official Bulletin 613–630 (23 June 2003), available at: http://bo.io.gov.mo/bo/i/2003/25/lei07.asp

[79] Article 5 (1) MFTL; ibid.

of its provisions. These sanctions include fines between 1.000 and 50.000 MOP for missing, inaccurate or deficient labeling information or else labeling information which is not consistent with the actual content (Article 19 (1) MLDL). Fines between 1.000 and 10.000 MOP are foreseen for the sale of foodstuff the expiry date of which has been exceeded or when the expiry date has been concealed by an additional sticker (Art. 19 (2) and (3) MLDL).

Not directly but merely indirectly addressing the issue of labelling fraud are also other laws. First, the Macau Food Safety Law (MFSL) foresees several administrative fines for the marketing of unsafe foodstuff or foodstuff that does not meet the hygiene standards (Articles 19 and 20 MFSL). In a certain sense, these provisions could be applied to labeling fraud too, as it is possible that food could generally be considered as safe but may become "unsafe" when it is used improperly due to false information provided on the label. Article 29 MFSL explains that the fines imposed under the food safety law are applied alternatively with the relevant provisions of the Penal Code.

Similarly, the Law 6/96/M establishing the legal regime governing violations against public health and the economy also contains several provisions that foresee fines for various violations against food safety, which apply in parallel to those contained in the Macau Penal Code.[80] The relevant fines include punishment for producing, preparing, manufacturing, transporting, storing, or selling or displaying for sale, importing, exporting or trading in any way unsafe food or food additives (Articles 20–22 Law 6/96/M). Particularly, Article 21 lit. a) Law 6/96/M foresees a fine for marketing food or food additives that are not abnormal but reveal a nature, composition, quality or source that does not match the description or attributes that are marketed.

Finally as far as the Macau Penal Code (MPC) is concerned, Article 269 MPC contains a provision establishing a crime for the corruption of food (or medicinal) products. Article 269 MPC is drafted based on the identical Article 282 of the Portuguese Criminal Code, which has been summarized as follows:

> Under article 282 of the Portuguese Penal Code (FOOD CORRUPTION) anyone who endangers the life or physical integrity of another person by corrupting, counterfeiting, concealing or modifying any edible, drinkable or chewable food substance (produced either for human consumption or health treatment), and/or reduces their nutritional or therapeutic value or adds any extra ingredient to them, will be sentenced to between 1 and 8 years in prison. This sentence may be reduced to a penalty of up to 3 years in prison, in case the criminal behaviour was negligent (i.e., not intentional), or to a penalty of up to 5 years in prison, if the danger was not intentionally created. The aforesaid penalty will also be reduced, or may even be waived, in case the agent willingly removes the threat of danger.[81]

In sum, the only legislation addressing labelling fraud directly is provided by the Macau Labeling Decree Law (MLDL). Indirectly, the Macau Food Safety law and the Law 6/96/M may be applicable as well. The relevant provision in the Macau

[80] Article 1 (2) Law No. 6/96/M, supra note 56.

[81] See João Matos Viana & Mariana Soares David, "Food Related Crimes", (2007) Criminal Law and Criminal Reform 5, available at: http://www.lexmundi.com/images/lexmundi/PDF/Member_News/MoraisLeitao_SpecialEdition2007Newsletter.pdf

Penal Code, however, does not seem to cover "labelling fraud" but mainly addresses the issue of corruption of food products.

Liability

Genetic Technology

As there is no specific regime for genetic technology in the present legal system of the Macau SAR, the specific issue of genetic liability appears to be governed by the general rules on liability laid down in various laws. First, the Macau Civil Code (MCC)[82] distinguishes broadly between contractual liability and civil liability (or torts). The first category results from a non-fulfillment of a contractual obligation whereas the second from the violation of absolute subjective rights. However, in this regard, it has been stated that "the boundary between these two areas is becoming ambiguous". This is because they share many common features and "in many new topics, like *culpa en contrahendo*, product liability, third party infringement of contract, pure economic loss etc., contractual liability and torts are barely distinguishable".[83] As for civil liability the relevant provision is Article 477 MCC, which areads as follows:

> Section V – Civil Liability
> Subsection I – Civil liability for unlawful facts
> Article 477 (General principle)
>
> 1. Anyone who, intentionally or with mere negligence, unlawfully breaches other person's right, or any legal provision intended to protect interests of third parties, shall have the obligation to compensate the injured party for the damage that resulted from the breach.
> 2. An obligation to compensate, irrespective of fault, only exists in cases especially provided for by the law.[84]
>
> With regard to the conditions of civil liability, the MCC distinguishes three main categories:
>
> 1. liabilities caused by unlawful facts which implies fault of the defendant (Articles 477–483 MCC);
> 2. liabilities where the fault of defendant is presumed (Articles 484–486 MCC); and
> 3. liabilities by risk (Articles 492–503 MCC).[85]

[82] Macau Civil Code (MCC) [Código Civil], approved by Decree-Law no. 39/99/M, of August 3, 1999, available at: http://bo.io.gov.mo/bo/i/99/31/codcivpt/

[83] See Tong Io Cheng, "Macau Contract Law", in Jacques H. Herbot (ed), International Encylclopaedia of Laws, vol. 9 (Alphen aan den Rijn: Kluwer Law International, 2009) 216.

[84] Translation by Jorge A.F. Godinho, "The Macau Civil Code – An Partial English Translation", available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1280595

[85] See Tong Io Cheng, supra note 83.

These are the main cases of liability laid down in the MCC. More specific rules on other forms of liability, such as product liability are governed by the Macau Commercial Code (MCC) which will be further discussed below.

As far as the extra-contractual civil liability of public entities is concerned, it is governed by the Decree-Law No. 28/91/M establishing the non-contractual civil liability regime of the Administration of the Territory [Macau SAR], collective public persons, its staff and agents for acts of public management.[86] The purpose of this law is to define the types of liability for unlawful acts in relation to the tasks of the public administration and to protect the legitimate interests and rights of individuals as well the scope of the duty to compensate them for injuries suffered. In this regard, Article 4 of the Decree-Law No. 28/91/M states that the fault of the staff and agents of public management is assessed based on Article 480 MCC, which states that "[I] is for the injured person to prove the fault of the agent, except if there is a legal presumption of fault" and that "[I]n the absence of other standard, fault shall be analyzed in accordance with the diligence of a good family father, considering the circumstances of the case".[87]

Finally, as it was already mentioned, the criminal liability related to food safety is laid down in Article 269 MPC and concerns mainly the corruption of food and not the labeling of food products.

Last but not least, it is important to mention that the Macau SAR's legal regime recognizes the liability of legal persons. With regard to food safety related matters, this is first and foremost recognized by the Macau Food Safety Law (MFSL) as laid down in Article 26 MFSL. A similar provision is found in Article 3 of the Law No. 6/96/M establishing the legal regime governing violations against public health and the economy.[88]

Product Liability

A more specific aspect of liability, namely liability related to products is regulated in the relevant provisions contained in Title VIII of the Commercial Code of Macau, which was adopted in 1999 and amended three times since then.[89] The relevant

[86] Decree-Law No. 28/91/M Establishing the non-contractual civil liability regime of the Administration of the Territory [i.e. Macau SAR], collective public persons, its staff and agents for acts of public management [Decreto-Lei n.° 28/91/M – Estabelece o regime da responsabilidade civil extracontratual da Administração do Território, pessoas colectivas públicas, seus titulares e agentes por actos de gestão pública], (1991) 16 Official Bulletin 1994, available at: http://bo.io.gov.mo/bo/i/91/16/declei28.asp

[87] Translation by Jorge A.F. Godinho, "The Macau Civil Code – An Partial English Translation", available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1280595

[88] See Law No. 6/96/M, supra note 56.

[89] Commercial Code of Macau (MCC) [Decreto-Lei n.° 40/99/M – Aprova o Código Comercial], Official Bulletin No. 31/1999, Series I, p. 2366 (August 3, 1999), available at: http://bo.io.gov.mo/

provision is Article 85 MCC, which stipulates the civil liability of a commercial entrepreneur as follows:

> Article 85 (Objective liability of producer commercial entrepreneur)
>
> 1. A producer commercial entrepreneur is liable, regardless of fault, for damage caused to third parties by the defects of products that he puts in circulation.
> 2. A producer is the manufacturer of a finished product, of a component part or of a raw material, and also whoever presents himself as such through the apposition of his name, trademark or other distinctive sign to the product.
> 3. The following are also considered as producers:
>
> anyone who, in the exercise of his enterprise, imports products for sale, lease, financial lease or another form of distribution;
>
> the distributor of products whose Macao producer or importer is not identified, except if, after being notified in writing, he communicates to the injured party the identity of one or the other, or of some preceding distributor, also in writing.[90]

Of great relevance to the issue of foodstuff, the following provision enshrined in Article 86 (1) MCC then defines the meaning of "product", which it defines as "any movable good" which can be "incorporated in another movable or immovable good". However, Art. 86 (2) MCC specifies that "products from the land, from raising livestock, fishing and hunting are excluded if they have not undergone any transformation". In the context of GMOs or other novel technologies, this text would, for instance, raise the question about the meaning of "transformation" and whether it is applicable to a GM modified tomato, for instance, which has been "transformed" as a seedling but not as a final product (i.e. a tomato as opposed to tomato ketchup). What constitutes a "defect" in the sense of Article 85 MCC is further explained in Article 87 (1) MCC where it states that "[A] product is defective if, at the moment of its entry into circulation, it does not offer the safety that legitimately is to be expected, having in account all circumstances, namely its presentation, characteristics and the use that reasonably can be made of it". Possibly relevant in a case concerning the liability of the commercial entrepreneur dealing with GM food may also be the exclusion from liability foreseen in Article 88 lit. e) MCC on the ground that "that the state of scientific and technical knowledge, on the moment in which he has put the product into circulation, did not allow the detection of the existence of the defect".

Summary

Legally speaking, Macau is "GMO free" in a sense that the existing laws and regulations do not explicitly address the issue of food safety concerns related to GMO products. In fact, however, this means that GMO products can be freely produced in and imported to Macau as long as they comply with the overall food safety related

bo/i/99/31/codcompt/. Please note that an unofficial English version of the MCC is available at: http://bo.io.gov.mo/bo/i/99/31/codcomen/

[90] Ibid.

laws and regulations. In this sense, Macau therefore can be considered an interesting case for the following two reasons: A first reason is found in the Macau SAR's special legal status as a so-called "Special Administrative Region (SAR)" of the People's Republic of China. This status establishes the Macau SAR as a "glocal actor", which can both regulate autonomously a wide range of local issues, while also taking part in the global arena, for instance, as a member of the World Trade Organization (WTO). To this legal speciality add various factors related to the special geographic, economic, historical and cultural background of the Macau SAR, of which – from the perspective of food safety – are worth mentioning its current status as the world's largest gaming hub, which on a land size of hardly 30 square kilometers inhabited by little more than half a million people, attracts annually more than 30 million people. To serve the needs of both the local population and millions of annual visitors, it offers a large number of food establishments as well as makes Macau almost entirely dependent on food imports from outside. Third and finally, from a regulatory perspective, Macau is also special because it is a free port and committed to free trade while at the same time, it is necessarily concerned with food safety issues. With regard to the latter, the debate about the specific and more casuistic consideration of food safety concerns related to novel technologies, such as notably biotechnology and nanotechnology as reflected in GM foods or nanofoods, as known from the European Union and People's Republic of China (PRC) has not yet arrived in Macau even though food belonging to both categories are likely to have been put in circulation in Macau already. This is interesting as it means less legal certainty, on the one hand, but perhaps also greater legal flexibility on the other hand, when it comes to comprise more recent or even future technological developments. This, ultimately, leaves open a possible answer to the question whether a more casuistic as opposed to a general regulatory approach is to be preferred.

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Questionnaire

AIDC Congres 2014 – IACL Congress 2014: Droit de l'environnement/Environmental Law

La technologie génétique et la sécurité alimentaire – Genetic Technology and Food Security

The following questions refer to every level of legislation and case law (international, supranational, national).

General Information

Use of GMO in Food Production

With regard to your country: Please provide a few details on facts and figures about the use of GMO, the public opinion on GMO and the position of the government on this matter.

Food Security

Is there a legal definition of food security in your country? What political concept lies beneath it? What role does genetic technology play in this context?

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Legal Superstructure

Please describe the relevant legal superstructure of genetic technology and food security law (e.g. right to food, basic rights, constitutional bases, and legal principles such as the precautionary principle).

Outline of the Relevant Law

Please outline the applicable law with regard to the interface between genetic technology law and food law. You may want to include international (e.g. Cartagena Protocol, Codex Alimentarius), supranational, national, and regional law.

Admission

Restriction of GMO

Are there legal provisions governing restriction of genetic technology such as moratoria, the invocation of safeguard clauses, subsidies for a GMO-free production or the voluntary renunciation of its use (e.g. "GMO-free zones")? Please outline the law concerning this question.

Admission of GMO in Food Production

What are in detail the legal requirements for the admission of GMO in food production and what procedures must be followed?

Threshold Values

Are there thresholds for GMO? If so, what types of legal threshold values exist for GMO? What are the legal consequences if thresholds are exceeded?

Implementation and Enforcement, Controlling Regime

How is the law concerning the admission of GMO implemented and enforced? How is compliance with the applicable law controlled?

Labelling Regime

Labelling

Is there law on food labelling, e.g. labels declaring food free of GMO or on the use of GMO for organic food? What are the contents of food labelling law concerning the use of GMO?

Legislation Addressing Labelling Fraud

How is labelling fraud in connection with the use of GMO being addressed (e.g. by unfair competition law)?

Liability

Genetic Technology

What is the legal nature of liability law governing genetic technology (civil law, public law, penal law)?

Please provide details on the conditions for liability (such as legal damage, causality, illegality, fault) and outline the legal consequences of breaches.

Product Liability

Please provide information on product liability law in the context of the use of GMO.

Summary

Please sum up the crucial topics addressed in your report and feel free to mention any additional information you find useful in the matter of genetic technology and food security.